THE UNIVERSITY OF QUEENSLAND

AUSTRALIA

THE INTER-RELATIONSHIP BETWEEN CLINICAL OUTCOMES AS MEASURED BY SAGITTAL PLANE ALIGNMENT OF IMPLANT COMPONENTS, PERI-OPERATIVE KINEMATICS, CLINICAL RATINGS SYSTEMS, STRENGTH, BALANCE AND FUNCTIONAL PERFORMANCE ASSESSMENT IN PATIENTS POST TOTAL KNEE ARTHROPLASTY

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A thesis submitted for the degree of Doctor of Philosophy at

The University of Queensland in 2017

School of Medicine

ABSTRACT

Background

Total Knee Arthroplasty (TKA) is a surgical procedure to replace the weight-bearing surfaces of the knee joint in order to relieve pain and disability from osteoarthritis and other arthritic conditions. The surgery involves resecting the diseased or damaged joint surfaces of the knee and resurfacing with metal and polyethylene prosthetic components shaped to allow continued motion of the knee and relief from pain.

The gold standard for measurement of success of TKA used by national joint registries is the ‘time to revision’ with a 92.8% fourteen year implant survival rate for primary TKA in Australia. With significant improvements in implant design and survival, most patients are primarily concerned about objective functional outcomes such as knee kinematics and strength to evaluate the success of their total knee arthroplasty (TKA). It is estimated that up to 23% of patients are dissatisfied with their replaced knee due to residual pain or limited range of motion and function. Therefore, various subjective and objective surrogate measures of outcome have been devised to obtain a better reflection of success post TKA. However, there is no consensus in regards to the most optimal, consistent and reliable outcome measure.

Aim and Objective

The aim of this research project was to investigate the inter-relationship between the clinical outcomes as measured by the sagittal plane alignment of implant components, peri-operative kinematics, validated clinical rating systems, strength, balance and functional performance tests in patients at least one year post TKA at a regional academic hospital. The primary objective was to investigate the correlation between the radiographic alignment of the femoral and tibial implant components in the sagittal plane and the post-operative kinematic data in patients who have undergone navigational total knee arthroplasty. This research project had two secondary objectives. The first was to investigate the influence of strength, post-operative range of motion (ROM) and Timed Up and Go (TUG) on balance. The second was to investigate how the strength, post-operative ROM, TUG and balance contribute to two validated clinical rating systems - Oxford Knee Score (OKS) and Knee Society Score (KSS).

Setting and Design

This was a retrospective, observational, cohort study of 94 patients (105 knees) who had undergone TKA from February 2009 to December 2012 by two consultant orthopaedic surgeons at the Rockhampton Hospital (RBH).

Methodology and Material

The list of participants was extracted from the computer-assisted total knee arthroplasty (CAS TKA) database. The pre- and intra-operative kinematic data - maximum flexion angle (MFA), maximum extension angle (MEA) and ROM was extracted. The sagittal plane component alignment was determined by measuring the femoral implant flexion/extension angle (sFCA), the posterior condylar offset (PCO), and the tibial implant slope (TS) on existing post-operative lateral radiographs.

Clinical outcome measures were collected during the regular post-operative patient follow-up at the Orthopaedic Outpatients Clinic. These comprised of two validated rating scores – Oxford Knee Score and Knee Society Score; measurement of isometric strength (flexion and extension) and balance using a Nintendo Wii platform; and assessment of function using the Timed ‘Up & Go’ (TUG) test. All the data collected was then combined, de-identified and analysed - descriptive analysis of all measured variables followed by multiple linear regressions to identify predictors of post-operative kinematics, balance and clinical rating systems. All analyses were conducted using STATA SE for Windows and a p-value less than 0.05 was considered statistically significant.

Results

Although the MFA was influenced by gender (p=0.04); age, gender and pre-operative kinematics did not otherwise influence post-operative knee kinematics. The prediction model for MFA was statistically significant (p=0.03) and accounted for 8.4% of the variance. FCA (R^2=0.3, p=0.01) and PCO (R^2=0.2, p=0.05) were statistically significant predictors of MFA. However, the prediction models for ROM and MEA did not achieve statistical significance. FCA (R^2=0.2, p=0.02) was also a statistically significant predictor with ROM.

Extension strength, Flexion strength, ROM and TUG were used in regression analyses to predict balance. TUG was the only significant moderate predictor of balance on a single leg with eyes open (R^2=0.2, p=0.05).

Multiple linear regression analysis with OKS as the dependent variable achieved statistical significance ($p<0.001$) and accounted for 35.2% of the variance. ROM ($R^2=0.1$, $p=0.02$) and TUG ($R^2=-0.9$, $p<0.001$) were both found to be statistically significant predictors of OKS.

Conclusion

The most important findings of this study are that the FCA demonstrates weak positive correlation with MFA and ROM and that PCO demonstrates weak positive correlation with MFA. However, TS does not contribute significantly to knee kinematics after TKA. This is clinically relevant as orthopaedic surgeons can increase the PCO in cruciate retaining TKA and the FCA within therapeutic limits to improve knee kinematics. Flexion strength, extension strength and ROM are unlikely to be significant predictors of balance. However, TUG is a moderate predictor of balance confirming the close relationship between walking ability and balance. Moreover, this study demonstrates that TUG and ROM are moderate predictors of OKS and that strength and balance are unlikely to contribute to patient satisfaction after TKA.

DECLARATION BY AUTHOR

This thesis is composed of my original work, and contains no material previously published or written by another person except where due reference has been made in the text. I have clearly stated the contribution by others to jointly-authored works that I have included in my thesis.

I have clearly stated the contribution of others to my thesis as a whole, including statistical assistance, survey design, data analysis, significant technical procedures, professional editorial advice, and any other original research work used or reported in my thesis. The content of my thesis is the result of work I have carried out since the commencement of my research higher degree candidature and does not include a substantial part of work that has been submitted to qualify for the award of any other degree or diploma in any university or other tertiary institution. I have clearly stated which parts of my thesis, if any, have been submitted to qualify for another award.

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Publications during candidature

Peer-Reviewed Papers

1. Antony J, Tetsworth K, Hohmann E. Influence of Sagittal Plane Component Alignment on Kinematics after Total Knee Arthroplasty. Knee Surg Sports Traumatol Arthrosc, 2016. doi: 10.1007/s00167-016-4098-x

Conference Poster Presentations

1. Antony J, Tetsworth K, Bryant A, Clark R, Hohmann E. Objective Predictors of Subjective Patient Satisfaction Post Total Knee Arthroplasty. Australian Orthopaedic Association Annual Scientific Meeting, Brisbane, Australia. 11-15, October, 2015.

2. Antony J, Tetsworth K, Bryant A, Clark R, Hohmann E. Total Knee Arthroplasty – The Influence of Post Operative Functional Outcome Measures on Balance. Australian Orthopaedic Association Annual Scientific Meeting, Melbourne, Australia. 12-16, October, 2014.

Publications included in this thesis

No publications included.

Contributions by others to the thesis

Professor E. Hohmann contributed significantly to the conception of the project with minor contributions from Associate Professor A. Bryant. Dr. R. Clark significantly facilitated data collection by providing access to software to measure balance and strength using Nintendo Wii platforms. Professor E. Hohmann contributed significantly to statistical analysis of data. Professor E. Hohmann and Associate Professor K. Tetsworth contributed significantly to drafting and editing of written work.

Statement of parts of the thesis submitted to qualify for the award of another degree

None

ACKNOWLEDGEMENTS

I would like to thank Professor E. Hohmann for the opportunity to undertake clinical research in the field of Surgery at the School of Medicine, University of Queensland. I am grateful for his excellent supervision, sound advice, remarkable patience and encouragement throughout the study.

I wish to express my thanks to all colleagues for their useful discussions and technical advice. I thank Dr. R. Clark for providing access to his software to facilitate measurement of balance and strength using the Nintendo Wii platform. I thank Associate Professor K. Tetsworth and Associate Professor A. Bryant for their valuable discussions and suggestions.

I thank the University of Queensland for financial assistance in the form of the University of Queensland Research Scholarship (UQRS) throughout the duration of my PhD candidature. This support was critical in the successful completion of the study.

I would like to dedicate this thesis to my dear father, mother, brother and most of all to my wife whose love and patience during these difficult years is much appreciated.

Keywords

Total Knee Arthroplasty, Outcome, Alignment, Flexion, Extension, Range of Motion, Strength, Balance, Patient Reported Outcome Measure

Australian and New Zealand Standard Research Classifications (ANZSRC)

ANZSRC code: 110323, Surgery, 100%

Fields of Research (FoR) Classification

FoR code: 1103, Clinical Sciences, 100%

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LIST OF ABBREVIATIONS USED IN THE THESIS

Abbreviation	*Full Form*
6MW	***Six Minute Walk Test***
ACL	***Anterior Cruciate Ligament***
BBS	***Berg Balance Scale***
BMI	***Body Mass Index***
CAS	***Computer-Assisted***
cFCA	***Femoral Component Angle in the Coronal Plane***
CoP	***Centre of Pressure***
CT	***Computed Tomography***
cTCA	***Tibial Component Angle in the Coronal Plane***
DMARD	***Disease Modifying Anti-Rheumatic Drugs***
IKDC	***International Knee Documentation Committee***
KOOS	***Knee Injury and Osteoarthritis Outcome Score***
KOOS-PS	***Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form***
KOS-ADL	***Knee Outcome Survey Activities of Daily Living Scale***
KSS	***Knee Society Score***
MCID	***Minimum Clinically Important Difference***
MEA	***Maximum Extension Angle***
MFA	***Maximum Flexion Angle***
MRI	***Magnetic Resonance Imaging***
NHMRC	***National Health and Medical Research Council***
OA	***Osteoarthritis***
OKS	***Oxford Knee Score***
PCL	***Posterior Cruciate Ligament***
PCO	***Posterior Condylar Offset***
PROM	***Patient Reported Outcome Measure***
PSPG	***Patient Specific Positioning Guides***
RA	***Rheumatoid Arthritis***
RBH	***Rockhampton Base Hospital***
ROM	***Range of Motion***
SCT	***Stair Climbing Test***

sFCA	***Femoral Component Angle in the Sagittal Plane***
SH-36	***Short Form - 36***
SLEO	***Single Leg Eyes Open***
TKA	***Total Knee Arthroplasty***
TLEO	***Two Legs Eyes Open***
TLEC	***Two Legs Eyes Closed***
TS	***Tibial Slope***
TUG	***Time Up and Go***
WOMAC	***Western Ontario and McMaster Universities Arthritis Index***

CHAPTER 1 -

Introduction

1.0 INTRODUCTION

1.1 Key Concepts

There has been a significant increase in the number of Total Knee Arthroplasty (TKA) procedures being performed every year since its introduction in 1973 [1-3]. Failure of TKA has traditionally been measured by time to revision [1, 2]. However, one in five patients are dissatisfied with the outcome of the operation without necessarily requiring a revision [4]. Patients most commonly attribute their dissatisfaction to persistent pain, lack of improvement in function and perception of alignment [1, 4]. Complex interactions between the patient, the surgeon and the implant dependant factors contribute to the outcome of TKA [4, 5].

Historically, alignment has received great attention as an important objective determinant of outcome and implant survival from laboratory investigations demonstrating correlation with increased stress and wear of the polyethylene component [5, 6]. Numerous methods and techniques such as Computer-Assisted (CAS) TKA, patient specific positioning guides (PSPG), mobile bearing TKA and high flexion TKA have been devised to improve component and overall alignment [7-9]. A recent randomised control study by Todesca et al, demonstrated superior accuracy of implant positioning and improved functional outcome in patients who underwent CAS TKA compared to conventional TKA [10].

As a result of the persisting patient dissatisfaction in spite of the improvement in alignment, there has been a drive to obtain patient reported outcome measures [1]. National joint registries such as the Swedish, New Zealand and England, Wales and Northern Ireland have utilised patient reported outcome measures since 1997 for the purpose of quality improvement [11-13]. Patient reported questionnaires such as the OKS, Western Ontario and McMaster Universities Arthritis Index (WOMAC), KSS, Knee Injury and Osteoarthritis Outcome Score (KOOS) and Lysholm Knee Scoring Scale have been utilised as cost-efficient, reproducible and reliable outcome measurement tools [14]. However, these clinical rating systems have issues of their own, particularly the lack of a minimum clinically important difference, purpose-specific utility, validation across languages and interpretational challenges [1, 14].

Therefore, it is important to complement these subjective measures of outcome with objective outcome measures such as strength, balance, proprioception and functional performance assessments [1]. Laubenthal et al, demonstrated that a minimum ROM of 90 degrees is required for activities of daily living with higher level activities like running and cycling dependant on increased ROM [15]. More recently, Ha et al, demonstrated that increased ROM post TKA is an important factor for functional outcome and patient satisfaction, particularly in the Asian population [16]. Quadriceps and hamstring strength provide further objective measures of clinical outcome in patients post TKA as they been attributed to the return of normal gait pattern [17]. Age and osteoarthritis are associated with the destruction of proprioceptive fibres and deterioration in balance with documented improvement post TKA resulting in decreased falls risk [18, 19]. There has been increased reliance on functional performance assessments such as TUG, six-minute walk (6MW) test and stair climbing test (SCT) to determine the functional ability in orthopaedic wards and to predict falls-risk [20].

Although these outcome measures in isolation have serious limitations, supplementing subjective and objective outcome measures provide a better reflection of patient satisfaction and function post TKA [1, 21]. However, the correlation between and the extent of influence of the outcome measures on each other is largely unknown [1]. Identifying the pivotal outcome measures will enable the orthopaedic community to focus attention and allocate resources to ensure an increase in success rates of TKA.

1.2 Rationale and Research Approach

1.2.1 Rationale:

Historically, both subjective and objective outcome measures have been used by orthopaedic surgeons to quantify the success of TKA [1]. There has been considerable disagreement about the most optimal, reliable, reproducible and cost-effective outcome measure [1, 14]. Whilst alignment has been perceived as one of the most important determinants of implant survival, alignment in the sagittal plane and its relationship to outcome as measured by intra-operative navigational kinematics has not been understood [5, 6]. Hence, this research will facilitate understanding of the relationship between sagittal plane alignment of implant components (sFCA, PCO, tibial slope) and post-operative kinematics (MFA, MEA and ROM).

Balance is a key outcome measure as it is predictive of the quality of life and functional ability of patients post TKA [22, 23]. Although it is known that TKA results in an improvement in balance, the relationship between balance and both subjective and objective clinical outcome measures is not well understood [18, 23]. Hence, this research will investigate the relationships between balance and outcome as measured by quadriceps and hamstring strength, post-operative ROM and TUG.

Subjective outcome measures such as OKS and KSS have been used as a reproducible, cost-effective method of measuring outcome in patients [14, 24]. These clinical rating systems have undergone validation and have been used extensively for assessing patients post TKA [14]. However, the inter-relationship between subjective and objective outcome measures has been largely unanswered [1, 21]. Hence, this research will investigate the relationship between subjective outcomes as measured by KSS and OKS and objective outcomes as measured by quadriceps and hamstring strength, post-operative ROM and TUG.

1.2.2 Research approach:

This research project was designed as a retrospective, observational, cohort study. The cohort was defined as patients who underwent CAS TKA at RBH from February, 2009 to December, 2012.

1.3 Background and Motivation

The research candidate is a medical graduate from the University of Queensland working as a junior doctor at the Royal Brisbane and Women's Hospital with a keen interest in the field of surgery. Therefore it was quite natural to select a research topic relevant to surgery for the purpose of this research higher degree. Being a medical alumnus of the University of Queensland and being familiar with its global research reputation, the decision was made to pursue the research higher degree at this institution. Great surgeons like Dr. Harvey Cushing and Sir John Charnley, were not only good clinicians, but they also devoted their time to extensive research and academics. I wish to follow in the footsteps of these individuals who I consider my role models and hope that the concurrent MBBS/PhD program of the Clinician Scientist Pathway at the University of Queensland will enable me to improve my clinical acumen while helping me become a good researcher and academic.

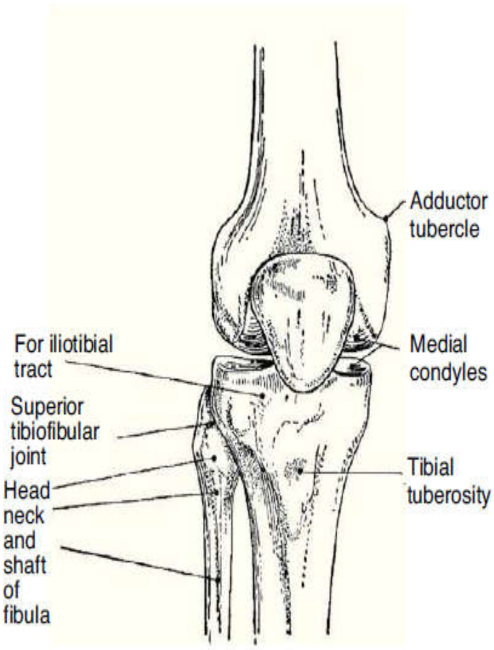
CHAPTER 2 -

Review of Literature

2.0 LITERATURE REVIEW

2.1 Anatomy of the Knee Joint

2.1.1 Bone:



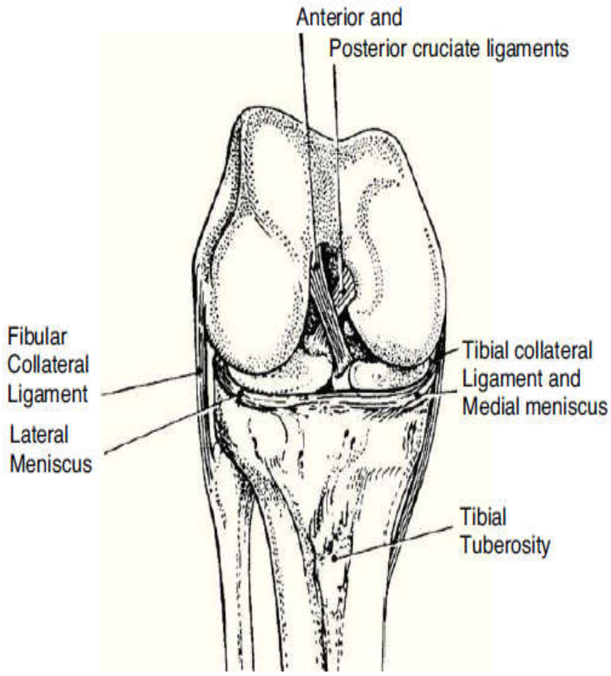


Fig 1: Anterior view of the knee joint with and without the patella [25]

The knee joint is a complex hinge joint permitting flexion, extension and slight rotation and gliding [25, 26]. It is formed by the articulation of four bones i.e. the femur, the tibia, the fibula and the patella as demonstrated in Fig 1 [26]. Orthopaedic surgeons describe three compartments of the knee joint: medial, lateral and patellofemoral [26, 27]. The distal portion of the femur widens to form the articular surfaces i.e. the lateral and medial condyles [26]. Distally, the femur articulates with the lateral and medial condyles of the proximal tibia separated by the inter-condylar eminence [26]. Anteriorly, the inter-condylar fossa or trochlear groove of the femoral condyles articulates with the posterior patella [27]. The patella is the largest sesamoid bone in the body with a variable anatomy, but is usually flat, proximally curved and distally tapered as demonstrated in Fig 1 [28]. The shaft of the tibia and fibula are attached together by the interosseous membrane to form a syndesmosis [26].

2.1.2 Menisci:

The lateral and medial menisci are paired, crescentic fibro-cartilaginous discs that extend from the inter-condylar eminence to the periphery of the tibial plateau as demonstrated in Fig 2 [29]. While providing a cushion for weight bearing, it also deepens the articulations to provide increased stability like the glenoid and acetabular labrum of the shoulder and hip joint respectively [26, 29]. Hence, these menisci are thinner and concave in the middle and thicker and convex in the periphery [26, 30]. The periphery in comparison is also relatively well-vascularised from the capillaries branching off the fibrous capsule and synovial membrane allowing good healing [29]. The medial meniscus has a characteristic C-shape and adheres medially to the medial collateral ligament, anteriorly to the anterior cruciate ligament and posteriorly to the posterior cruciate ligament rendering it less mobile and susceptible to combined injury with the medial collateral ligament [29, 30]. The wider lateral meniscus has the tendency to get trapped between the femur and tibia causing "clunking" in some patients. It can be discoid shaped in 5% of the population [30].

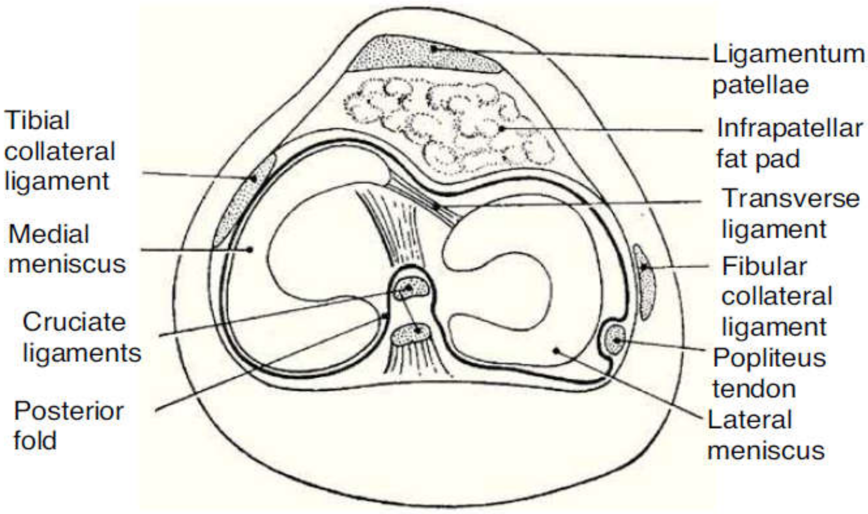


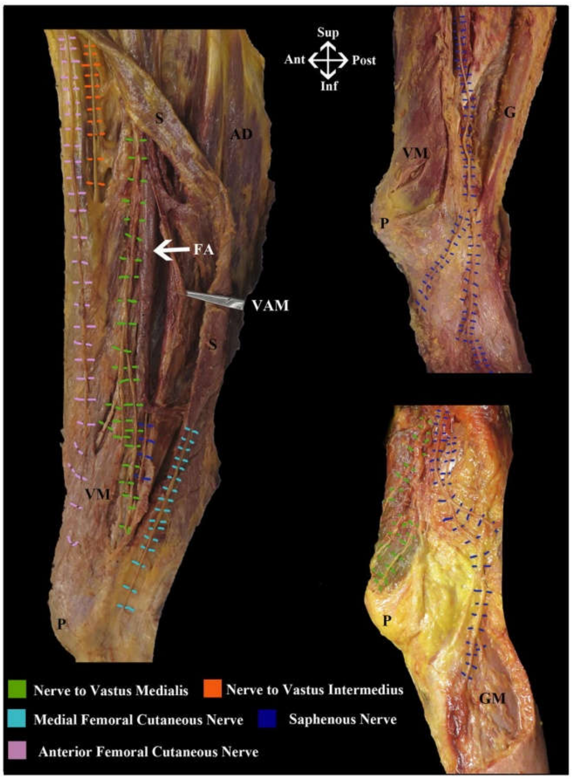
Fig 2: Intra-articular anatomy of the knee [25]

2.1.3 Ligaments:

The stability of the knee joint is maintained by a group of intra-articular and extra-articular ligaments [26]. The intra-articular ligaments are the anterior cruciate ligament, posterior cruciate ligament and the posterior meniscofemoral ligament [26, 30]. The anterior cruciate ligament originates from the anterior inter-condylar eminence of the tibial plateau and moves superior, posterior and lateral to attach to the postero-medial portion of the lateral femoral condyle [31]. The posterior cruciate ligament originates from the posterior inter-condylar eminence of the tibial plateau and moves superior, anterior and medial along the medial aspect of the anterior cruciate to attach to the antero-lateral portion of the medial femoral condyle [32]. There are significant inconsistencies in the presence and size of the meniscofemoral ligament which originates from the posterior horn of the lateral meniscus and inserts onto the medial femoral condyle adjacent to the posterior cruciate [29, 30]. The extra-articular ligaments are the patellar ligament, medial collateral ligament, lateral collateral ligament, oblique popliteal ligament and arcuate popliteal ligament [26]. The tendon of the quadriceps femoris completely surrounds the patella after which it becomes the patella ligament to attach to the tibial tuberosity [28]. The fibular collateral ligament, separated from the lateral meniscus by the popliteus tendon, originates from the lateral epicondyle of the femur and attaches to the fibular head [26, 33]. It protects the knee joint against varus stress [33]. The tibial collateral ligament originates from the medial epicondyle of the femur and attach to the medial condyle of the tibia [26, 34]. It protects the knee joint against valgus stress [33, 34]. An expansion of the semimembranosus tendon, the oblique popliteal ligament, originates from the medial tibial condyle and attaches to the lateral femoral condyle [26, 29]. The arcuate popliteal ligament originates at the fibular head, moves over the tendon of the popliteus and blends with the posterior fibrous capsule of the knee [25, 26]. Both the oblique and arcuate popliteal ligaments reinforce the joint capsule posteriorly [26].

2.1.4 <u>Innervation</u>:

Innervation of the knee joint is by the obturator and femoral nerves of the lumbar plexus and tibial and common peroneal nerves of the sacral plexus as demonstrated in Fig 3 [29, 35]. Sensation over the medial aspect of the knee is by the infrapatellar branch of the saphenous nerve [28, 36]. Sensation over the areas of knee is by the peripatellar plexus comprising branches of the femoral and lateral femoral cutaneous nerves [28, 35].



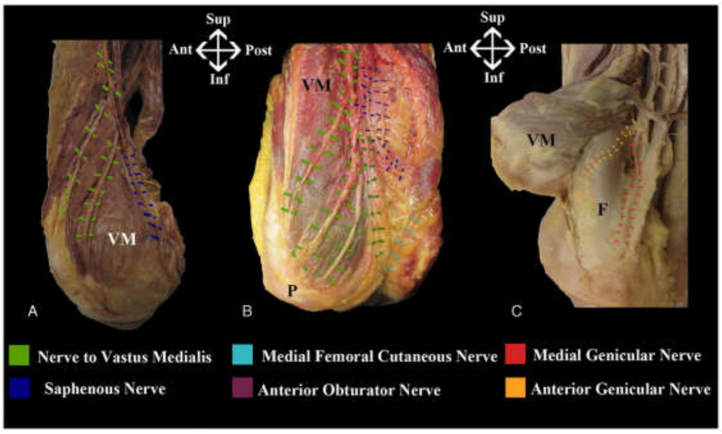


Fig 3: Innervation of the knee joint [36]

2.1.5 *Musculature:*

The knee joint is capable of flexion and extension with minimal internal and external rotation [26]. The primary extensors of the knee joint are the vastus medialis, vastus intermedius, vastus lateralis and rectus femoris which together form the quadriceps femoris [25, 26]. The primary flexors of the knee joint are semitendinosus, semimembranosus and biceps femoris [25]. Other weak flexors include gracilis, sartorius, gastrocneumius and popliteus [26]. Internal rotation is achieved by semimembranosus, semitendinosus, popliteus, gracilis and Sartorius [25, 26]. Lateral rotation of the knee is predominantly achieved by the biceps femoris [26].

2.1.6 *Vasculature:*

The knee joint is supplied by a rich arterial anastamosis formed by the popliteal artery (superior, middle and inferior genicular branches), femoral artery (descending genicular branch), lateral femoral circumflex artery (descending branch), circumflex fibular artery and tibial recurrent arteries (anterior and posterior) as demonstrated in Fig 4 [25, 37]. The venous drainage is by deep veins of the same name as the corresponding arteries and they follow the arterial system [25].

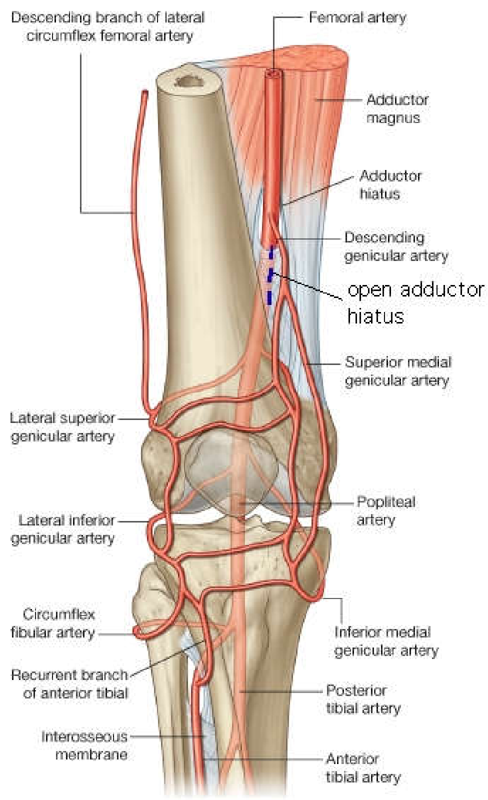


Fig 4: Vasculature of the knee joint [37]

2.1.7 *Bursae:*

There are numerous bursae that surround the knee [26]. Their arrangement around the knee is highly variable and complex [25]. The pes anserine bursa is located deep to the pes anserinus, formed by the tendons of gracilis, sartorius, and semitendinosus, 4-5cm inferior to the antero-medial joint line of the knee [25, 26]. The semimembranosus bursa can be found in the popliteal fossa [25]. Other bursae of clinical significance include the supra-patellar bursa, infra-patellar bursa and pre-patellar bursa [25, 26].

2.1.8 Joint capsule:

The joint capsule of the knee joint has two components [26]. The external fibrous layer is generally thin with localized thickenings due to the extra-articular ligaments of the knee [26, 29]. The internal synovial membrane lines the articular surfaces and produces synovial fluid which lubricates the knee joint and provides nutrients [26].

2.2 Pathology

Damage to any of the three compartments of the knee joint can be a result of osteoarthritis (idiopathic, post-traumatic), inflammatory arthritis (rheumatoid arthritis, sero-negative spondyloarthropathies, etc), osteonecrosis, tumours or congenital deformities [2].

2.2.1 Osteoarthritis:

Prevalence of osteoarthritis (OA) is increasing in the aging population with 10-12% of the adult population complaining of symptomatic OA knees [38]. OA generally affects the knees bilaterally with a resultant genu varus deformity due to medial compartment involvement [39]. The condition then progresses to involve the lateral and then the patellofemoral compartments, but the most affected compartment is often the medial compartment [38]. Factors predisposing to development of OA include obesity, heredity (family history), gender (females), hyper-mobility, trauma, joint congruity, occupation (miners – hip, knees, shoulder; farmers – hip; cotton workers – hand) and sport (repetitive use and injury) [39, 40]. Patients usually present complaining of joint pain, stiffness, instability and loss of function. A careful physical examination may elicit joint tenderness, crepitus, limited range of motion, instability, effusion and muscle wasting [39].

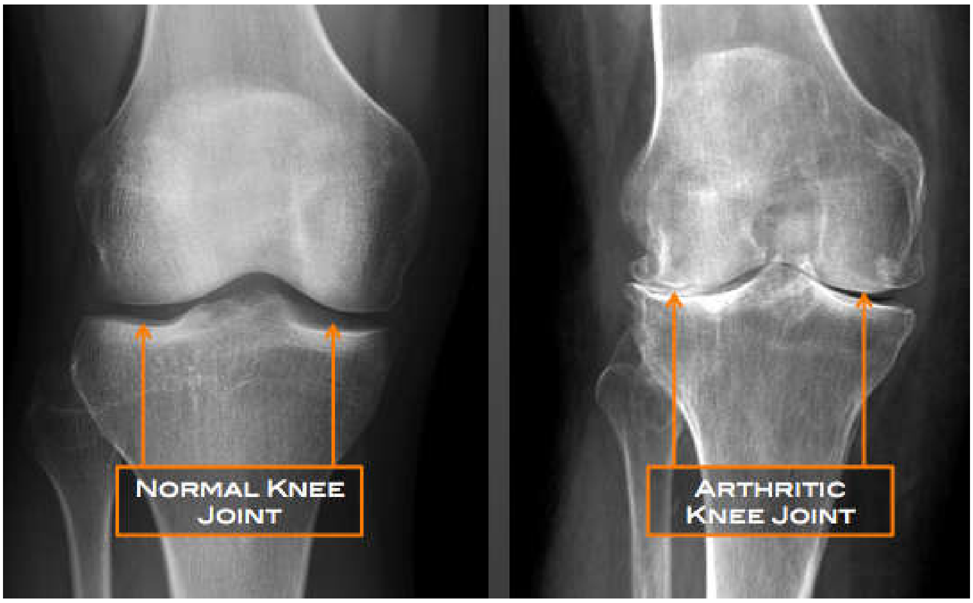


Fig 5: X-ray of normal and arthritic knee (IMPAX, Agfa HealthCare Corporation, Greenville, SC, USA)

Primary modality of investigation is plain radiography [40, 41]. Three views are commonly used: anteroposterior – obtained with the patient standing (stressed) to assess the medial and lateral compartments; lateral – standing to assess the patellofemoral joint narrowing and patellar position; tangential patellar view (sunrise, skyline or merchant view) – to assess patellofemoral compartment [28, 39]. Classic radiographic findings include joint space narrowing, subchondral sclerosis, subchondral cysts and osteophytes as demonstrated in Fig 5 [38, 42]. These radiographic findings can be graded to determine severity by using systems such as the Kellgren-Lawrence grading system and the Ahlback classification [42]. Advanced imaging modalities like Computed Tomography and Magnetic Resonance Imaging are not required in assessing OA joints for TKA, but may be useful in identifying other pathologies such as meniscal tears and osteonecrosis [39, 41].

2.2.2 *__Rheumatoid Arthritis:__*

Rheumatoid Arthritis (RA) is a systemic autoimmune condition that presents as slowly progressive, symmetrical, peripheral polyarthritis occasionally involving the knee joint as demonstrated in Fig 6 [43]. It often results in a genu valgus deformity and can be a precursor to OA [40, 43]. Laboratory investigations might reveal elevated Rheumatoid Factor and/or Anti-CCP with raised ESR/CRP [39]. Plain X-rays demonstrate joint space narrowing and juxta-articular osteoporosis [43].

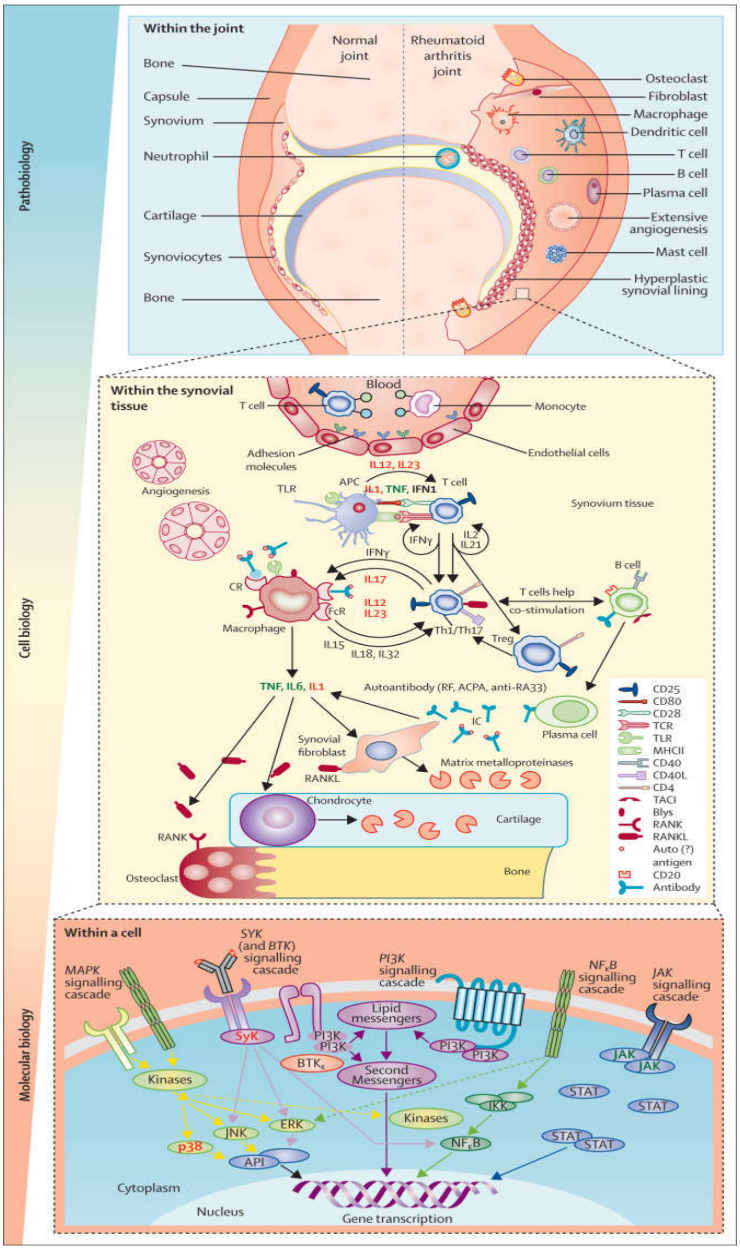


__Fig 6: Pathogenesis of rheumatoid arthritis [43]__

2.2.3 *Other pathology:*

Sero-negative spondyloarthropathies produce histologically similar synovitis to RA but without the production of rheumatoid factor and an increased association with HLA-B27 [44]. Osteonecrosis can be due to a multitude of factors such as sickle cell disease, Caisson's disease, medications, endocrine disorders (Cushing's and diabetes mellitus), trauma, HIV, irradiation and alcohol abuse [45]. It can present as joint pain with MRI being the best modality of investigation [39, 45].

2.3 Management

Treatment options for arthritic knees involve non-surgical and surgical management [40].

2.3.1 *Non-Surgical Management:*

Non-surgical management includes non-pharmacological management such as weight loss for overweight individuals; use of walking aids to take load off the knees; strengthening, stretching and conditioning exercises; use of heat/ice packs; wedge insoles or bracing [40, 46]. Pharmacological management involves use of paracetamol, NSAIDs, intra-articular corticosteroid injections and in the case of inflammatory arthritis DMARDs (disease modifying anti-rheumatic drugs) [40, 43]. Recent studies have reaffirmed the utility of autologous platelet rich plasma and hyaluronic acid in the treatment of mild to moderate osteroarthritis [47].

2.3.2 *Surgical Management:*

Surgical interventions include arthroscopy, osteotomy, arthroplasty and arthrodesis [40, 48, 49]. Arthroscopic synovectomy produces good outcomes in patients with diseased rheumatoid synovium, but the use of arthroscopic lavage and debridement in OA remains controversial and under investigation [48, 50]. Arthroscopic lavage and debridement in OA is strictly indicated for patients who experience mechanical symptoms such as locking-unlocking due to underlying meniscal pathology [40]. Osteotomy remains a viable option in younger patients with non-inflammatory, unicompartmental disease [40, 48]. A medial compartment localisation producing a genu varus deformity is amenable to a proximal tibial osteotomy and a lateral compartment localisation producing a genu valgus deformity is amenable to osteotomy of the supracondylar region of the distal femur [50]. Osteotomy in the selective case produces favourable outcomes although controversy surrounds the outcome of secondary conversion to a total knee arthroplasty [48, 50]. W-Dahl et al reported a 30% cumulative revision rate at 10 years for high tibial osteotomy with increased risk of revision in the female gender and with increasing age [51].

Unicompartmental knee arthroplasty began in the 1950s and is experiencing a current resurgence [48]. While detractors claim incomplete pain relief, early implant failure and increased difficulty of subsequent revisions, proponents attribute these to flaws in early designs [48, 50]. In Australia, the cumulative percent revision at 11 years for primary unicompartmental knee arthroplasty is 16.4% compared to 6.4% for primary total knee arthroplasty [2]. National joint registry data show that the risk of re-revision after a conversion from unicompartmental to TKA is also higher than if a TKA was performed as the primary procedure [1]. Unicompartmental knee arthroplasty has the advantage of preservation of ligamentous integrity restoring natural kinematics of the knee, less extensive surgery, lower risk of infection and preservation of bone stock of the remaining two compartments for subsequent revision surgeries [1, 52]. Indications for unicompartmental knee arthroplasty are strict and include – arthritic wear of single compartment; age and activity level compatible for arthroplasty; BMI less than 30kg/m^2; intact ligament system; and moderate axis deformity that is correctable to less than 7-10 degrees varus or valgus after tibial augmentation spacer [1, 50, 52]. Rheumatoid arthritis is considered a contraindication [52]. Arthrodesis or surgical fusion of the knee joint is often reserved as a salvage procedure for patients with multiple prosthetic infections/revisions or failed extensor mechanism [49]. This procedure has the advantage of pain relief, but compromises the functional ability of the knee joint and is hence considered a last resort [39, 48, 49].

2.4 Total Knee Arthroplasty

2.4.1 <u>Introduction to Total Knee Arthroplasty:</u>

Total knee arthroplasty (TKA) was first introduced by Insall and colleagues as the “total condylar prosthesis” at the Hospital for Special Surgery in 1973 [3]. Total Knee Arthroplasty (TKA) is a surgical procedure to replace the weight-bearing surfaces of the knee joint in order to relieve pain and disability from osteoarthritis and other arthritic conditions [1]. The surgery involves resecting the diseased or damaged joint surfaces of the knee and resurfacing with metal and polyethylene prosthetic components shaped to allow continued motion of the knee and relief from pain as demonstrated in Fig 7 [1, 53].

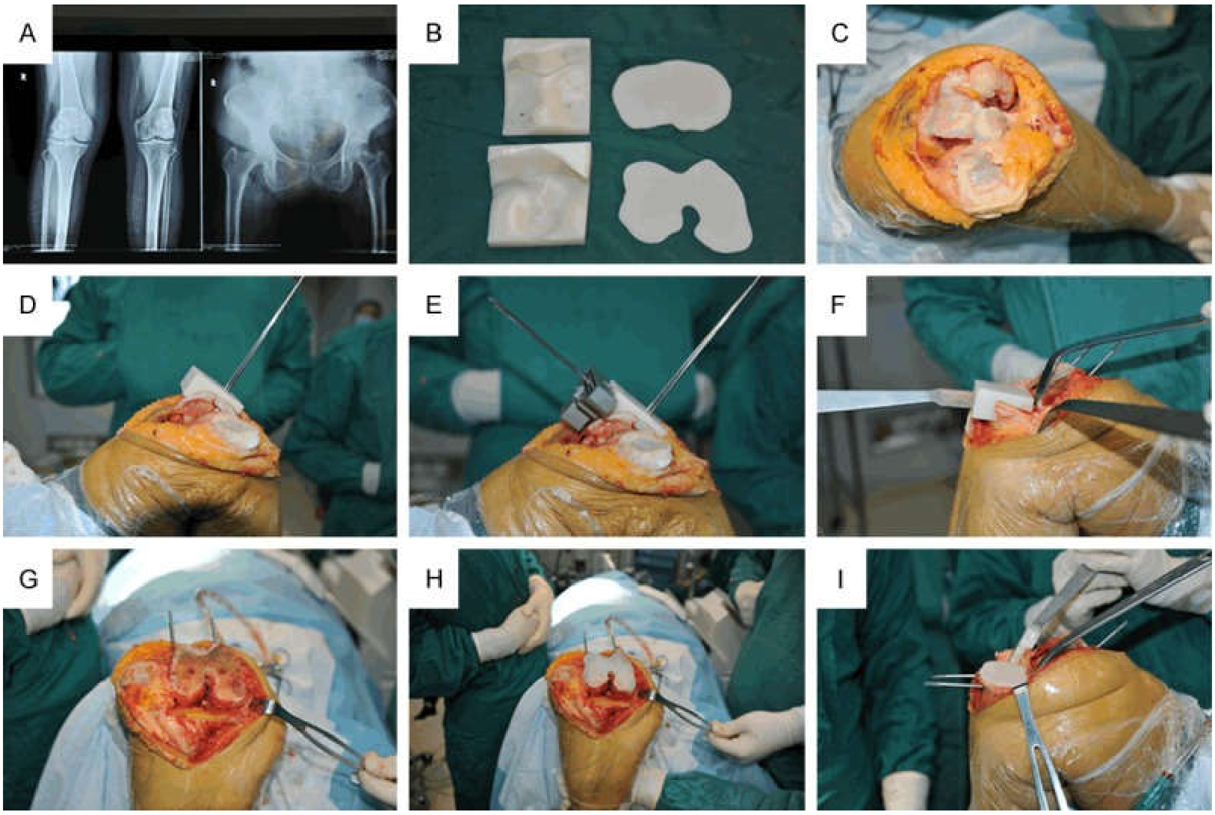


Fig 7: Total knee arthroplasty. A – anteroposterior radiographs of bilateral knees and hips; B – femoral and tibial components; C- incision to open the knee joint; D- attachment of jig to femur; E – femoral cuts and resection of bone; F – attachment of tibial jig; G – tibial cut and resection of bone; H – implantation of femoral component; I – implantation of tibial component [53]

TKA is conventionally performed with the aid of intra-medullary or extra-medullary jig-based alignments [54]. CAS TKA was introduced in 1997 and can utilise either image-based systems – preoperative CT or intraoperative fluoroscopy for collection of morphological information; or imageless systems – to overcome concerns about radiation exposure by using a virtual model supplemented by registration data [55]. CAS-TKA incorporates three basic components: the computer platform, the tracking system, and the rigid body marker [56]. Todesca et al, examined 225 patients prospectively and randomly assigned them to conventional and CAS TKA to demonstrate superior accuracy of implant positioning and better functional outcomes of CAS TKA [10, 57].

TKA can be posterior cruciate substituting where the PCL is excised; or posterior cruciate retaining when the PCL is preserved [58]. Fixation for TKA include cemented, cement-less or hybrid options [59]. The Cochrane review investigating the efficacy of fixation options for

TKA by Nakama et al, demonstrate smaller displacement of the tibial component with cemented fixation in the short term with increased subsequent risk of loosening and no demonstrable evidence of any difference in functional performance [59]. Cemented primary procedures have a lower rate of second revision compared to other methods of fixation when the first revision is undertaken with five years of the primary procedure. The method of fixation does not have an effect on the outcome of the first revision after five years [2].

TKA is considered to be both cost effective and highly successful with a one year mortality rate of 1.0% and a ten year mortality rate of 24% [2, 13]. By 2015, 534,717 knee replacements were performed in Australia of which 443,948 were primary TKA, 46701 were partial TKA and 44068 were revision knee replacements [2]. In Australia, the total number of TKA performed has increased by 88.3% since 2003 and 4.7% over the last year [2]. This is comparable to the Scandinavian countries such as Sweden where the incidence of TKA has more than doubled since 1998 [11]. This increase in incidence of TKA can be attributed to the increasing prevalence of osteoarthritis, accounting for 94-98% of TKAs performed, in an ever growing geriatric population [1, 2].

2.4.2 Indications and Contraindications:

The main indication for TKA is pain relief of arthritic knees confirmed by radiography that have failed prolonged non-surgical intervention and do not meet the indication for other surgical procedures [1, 20]. Restoration of function and correction of deformity are secondary outcomes in TKA and are not primary indications to perform the procedure [1, 39]. Absolute contraindications to perform TKA include evidence of an active infection, a non-functioning extensor mechanism and vascular compromise to lower extremity [1]. Neurological conditions such as polio, stroke and those that affect the lower extremities can be considered a relative contraindication, but neither age nor weight (BMI) is a contraindication to TKA [1, 60].

2.4.3 "Time to Failure/Revision" – Traditional Outcome Measure:

The gold standard for measurement of success of TKA used by national joint registries is the 'time to revision' with a 92.8% fourteen year implant survival rate for primary TKA in Australia [2]. The revision rate as measured by mean revisions per 100 observed component years varies between countries – Sweden: 0.71; Australia: 0.83; Norway: 1.27; Finland: 1.77; New Zealand: 1.93; Denmark: 2.51 [61]. The most common reason for failure, which accounts for 28.7% of all revisions, is aseptic loosening/lysis usually due to implant wear [1, 2]. Infections account for 22.4% of all revisions [2]. Contributors to failure also include postoperative pain (especially patellofemoral pain – 20.9%), instability (6.3%) and stiffness, which together contribute to a further 30-40% of all revisions [1, 2]. Numerous factors increase the risk for failure and revision [1, 11]. Age, an important prognostic factor is inversely related to the risk of revision with 2.5 times higher revision rates in patients who are younger than 65 years of age [2, 11]. Males also have a significantly increased risk of revision due to a higher incidence of prosthetic infections [2]. The diagnosis is known to influence outcome with primary TKA for rheumatoid arthritis demonstrating lower revision rates and that for osteonecrosis and other inflammatory arthritis demonstrating higher revision rates than that for OA [2, 11]. The class and type of implants also affect the risk of revision and national joint registries keep an active record of failure rates to identify implants that perform poorly [11]. Other factors include patient dependant factors such as obesity and surgeon dependant factors such as surgical technique, experience, skill and postoperative care protocol [1, 2, 62]. However, determining the success of TKA purely by assessing the 'time to revision' is not reflective of patient satisfaction and functioning on a daily basis and could potentially underestimate problems experienced post TKA.

2.4.4 Other Outcome Measures:

It is estimated that up to 23% of patients are dissatisfied with their replaced knee due to residual pain or limited range of motion and function [1, 4]. Therefore various subjective and objective surrogate measures of outcome have been devised to obtain a better reflection of success post TKA [1]. However, there is no consensus in regards to the most optimal, consistent and reliable outcome measure.

2.4.4.1 Range of Motion:

One of the primary outcomes that most patients are concerned about is the ROM acquired by the knee post surgery [63, 64]. Laubenthal et al, demonstrated that a minimum ROM of 90 degrees is required for activities of daily living with higher level activities like running and cycling dependant on increased ROM [15]. More recently, Ha et al, demonstrated that increased ROM post TKA is an important factor for functional outcome and patient satisfaction, particularly in the Asian population [16]. The factors suspected of contributing to the post TKA kinematics have been extensively investigated [63-65]. The most reliable predictor of post-operative ROM is pre-operative ROM [64-66]. This could be due to periarticular soft tissue contractions resulting in a soft tissue imbalance and requiring soft tissue releases in carefully selected cases [6, 65]. Posterior cruciate substituting prosthesis is associated with statistically significant improvement in range of motion in comparison with cruciate retaining prosthesis [58, 67, 68]. Ishii et al, investigated the change in ROM during pre-operative, intra-operative and post-operative periods across posterior cruciate ligament sacrificing and retaining prostheses [66]. Significant correlations were observed between 'pre-operative and intra-operative ROM' and 'pre-operative and post-operative ROM' across both prostheses [66]. Factors suspected of influencing the postoperative ROM and still under investigation include gender, implant design, patellar resurfacing, patellar height and postoperative physiotherapy [63-65, 67].

Knee extension ROM is significantly correlated with extensor mechanism strength and physical function as assessed by Short Form 36 (SF-36) [69]. ROM, flexion contractures and extension lag also contribute to the calculation of KSS [70]. Hence, the ROM acquired post-operatively does influence both subjective and objective clinical outcome measures. Although, there is a significant correlation between 'intra-operative and post-operative ROM' in patients who underwent posterior cruciate sacrificing TKA, the influence of intra-operative kinematic data on outcome measures is not well understood and warrants further investigation [66].

2.4.4.2 Strength:

Another outcome measure is the flexion and extension strength after TKA as patients are concerned about their ability to climb stairs and engage in physical activities [17, 71]. Quadriceps strength is intricately associated with performance and the loss of extensor mechanism could result in a collapse when the knee is flexed [5, 71]. Quadriceps weakness due to atrophy and neuromuscular activation deficits is intrinsic to the pathogenesis and natural progression of osteoarthritis [71]. There is an immediate decline in the strength of the extensor mechanism immediately post TKA attributed to the surgical approach and knee swelling followed by significant improvement which plateaus after six to twelve months [71-73]. Factors that contribute to quadriceps strength post TKA include early surgery, implant design, surgical approach, neuromuscular electrical stimulation, extension ROM and post-operative rehabilitation [20, 60, 69]. Currently, hamstring strength is attributed decreased functional significance compared to the extensor mechanism as hamstring weakness only becomes apparent in high intensity activities like running and uphill walking [17, 71].

However, as the incidence of TKA in the younger population increases, hamstring strength will acquire enhanced functional significance [17].

2.4.4.3 Clinical Outcome Rating Systems:

Numerous outcomes scores such as International Knee Documentation Committee (IKDC), Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale and Activity Rating Scale (ARS) have been used to investigate the outcome of TKA [14]. The limitation faced by outcome scores is the inability to objectively assess the function of the knee without being biased by the overall function of the patient [24, 74]. A major limitation is the lack of a minimum clinically important difference (MCID) i.e. the least difference in scores that demonstrate a clinically significant difference [14]. These rating systems are limited also by their lack of validation across languages and their purpose specific utility – a rating system validated for tibial plateau fractures cannot then be used to assess outcome of cruciate reconstruction despite being an indicator of knee function unless subsequently also validated in cruciate reconstruction patients [1, 14]. The different outcome scores variably weigh the different factors (pain, function, ROM) contributing to outcome and opinions vary about the most appropriate clinical rating system [14, 74]. The Western Ontario and McMaster University Osteoarthritis Index (WOMAC), SF-36, Oxford Knee Score (OKS) and Knee Society Score (KSS) have undergone validation and demonstrate sufficient inter-rater reliability for assessment of outcome [70, 74]. The OKS is a 12-item questionnaire for patients undergoing TKA that assesses outcome in the last 4 weeks with a score out of 48 [14]. It demonstrates good sensitivity to change in outcome and adequate internal consistency across multiple languages [14, 74]. It has been widely accepted due to its simplicity and ease of use with the lack of a minimum clinically important difference being a major weakness [14]. The original KSS was developed in 1989 and included a knee score to assess the knee and a functional score to assess the ability to undertake activities of daily living [24]. This was later abandoned to make way for the new KSS that is broadly applicable across sex, age, activity level and implant type [24, 70]. The KSS is a validated and responsive questionnaire to assess both subjective and objective performance before and after TKA [70]. Rating systems, most of which are self-reporting questionnaires, fail to reflect physical ability and overestimate performance [21].

2.4.4.4 Proprioception and Balance:

Balance and proprioception are important predictive factors for the quality of a patient's life and the functional level achieved post TKA [22]. There is a steady decline in proprioception with age even in patients with normal knees [23]. Moreover, the pathogenesis of osteoarthritis also involves loss of the proprioceptive ability of the knee from destruction of intra-articular cartilage, ligaments and tendons which result in deteriorating balance and increased falls-risk [19, 23]. Despite this destruction of intra-articular proprioceptive structures, TKA seems to restore the soft tissue balance and hence the proprioceptive ability of the extra-articular structures resulting in a decline in falls-risk, atleast in the short term [23]. Improvement in balance and proprioception is observed in the first 6 months post surgery after which it plateaus [75, 76]. Bascuas et al, analysed the relationship between balance and clinical outcome measures such as BMI, pain, range of motion, strength (flexion and extension), gait velocity and KSS in 44 patients [18]. A statistically significant negative correlation was demonstrated between age and improvement in balance [18]. Schwartz et al, also demonstrated a statistically significant positive correlation between balance and the clinical outcome measures - SF-36, OKS, TUG and four square step test [22]. Balance is also better in patients with bilateral TKA as opposed to unilateral TKA [77]. Other factors that predict/influence balance and proprioception include preoperative proprioceptive training, joint space, mal-alignment, soft tissue balance and early postoperative rehabilitation [19, 75, 78-80].

2.4.4.5 Timed Up and Go:

Although clinical rating systems are efficient and cost-effective, there is growing evidence for the inclusion of performance tests such as Berg Balance Score (BBS), TUG, 6MW test and SCT in the analysis of TKA outcomes [20, 21]. The TUG test is considered to be a reliable and valid measure of change in functional mobility of inpatients in orthopaedic wards, but is not a good predictor of length of stay [81]. Beauchet et al, demonstrated that TUG is closely associated with a past history of falls [82]. Although, its potential to predict future falls is limited, there is an improvement in correlation with standardization of testing conditions and control of significant potential confounders such as age, gender and co-morbidities [21, 82]. Poor performance in these functional tests preoperatively is strongly associated with poor performance postoperatively [20, 82]. Other factors such as age and declining mental health also predict poor performance in functional tests [20].

2.4.5 Role of Alignment in TKA:

The alignment of implant components is a surgeon dependant factor that improves with experience and skill and demands significant attention and resources [5, 83]. The surgeon attempts to restore the overall alignment of the limb to pre-disease state by carefully aligning the implant components in the coronal, sagittal and transverse planes with the joint line at an appropriate level and good soft tissue balance in flexion and extension without limiting the range of motion or putting undue pressure on the polyethylene plate [6]. Numerous strategies such as navigational TKA (CAS TKA), patient specific positioning guides (PSPG), mobile bearing prosthesis and high flexion TKA have been devised in order to minimize component and overall mal-alignment [7-9]. The alignment in TKA can be determined clinically or by employing radiography, fluoroscopy, the Perth CT protocol, MRI and navigational investigations with each modality subject to its inherent limitations [84, 85].

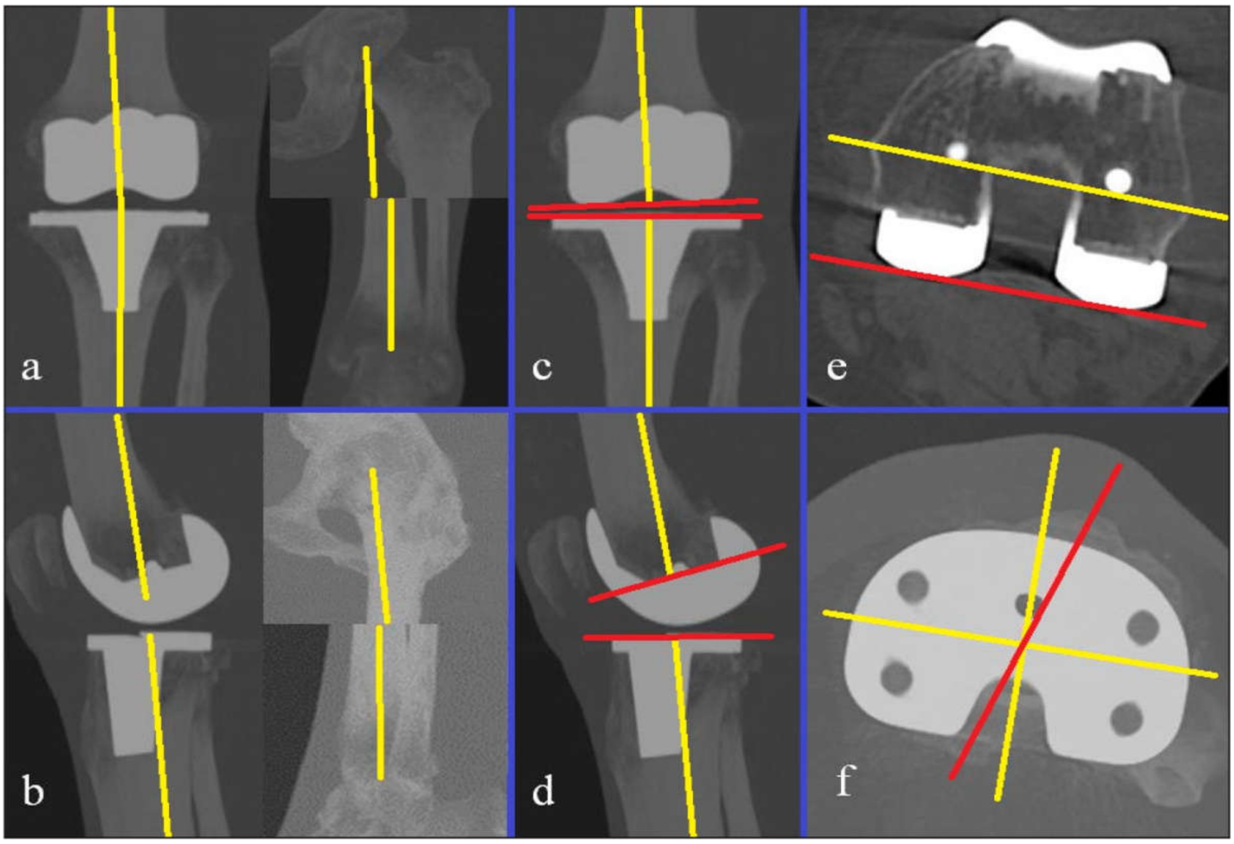


Fig 8: Alignment of femoral and tibial components in the coronal (a and c), sagittal (b and d) and transverse (e and f) planes [6].

Component mal-alignment can occur in three planes: the sagittal plane i.e. femoral component flexion/extension and tibial slope; the coronal plane i.e. femoral and tibial component valgus/varus; and the transverse plane i.e. femoral and tibial component rotation as demonstrated in Fig 8 [6]. The acceptable limits of implant alignment in total knee arthroplasty are considered to be very narrow [86]. Mal-alignment was attributed as the primary cause in only 2.2% of revisions after primary TKA [2]. This is because mal-alignment manifests as other modes of failure such as implant loosening/lysis, patellofemoral pain, instability, fracture, patellar erosion and implant wear thus contributing a more significant role in outcome/survival than directly attributed [2, 5]. However, the question of which alignment parameters are critical and their relative importance is still largely unanswered.

2.4.6 Overall Alignment:

The mechanical axis of the limb is the imaginary straight line drawn from the centre of the femoral head to the centre of the ankle as assessed on a long leg anteroposterior radiograph [6]. An off-centre loading would cause collapse on one side or lift-off on the other resulting in component loosening and thus failure [5]. Post operative limb alignment of 0±3 degrees relative to the mechanical axis is considered to maximize implant durability and improve clinical outcome [87, 88]. However, Parratte et al concluded that a strict adherence to a neutral postoperative mechanical axis did not improve implant survival [89]. Ritter et al, studied 6070 knees to define a neutral overall alignment as a tibiofemoral angle of 2.5-7.4 degrees valgus and demonstrated improved implant survival when this neutral alignment was achieved [62]. Hence, it is difficult to conclude on the ideal overall alignment for the population in general as it likely to be highly patient-specific.

2.4.7 Alignment in Transverse Plane:

Although there is a high variability in the reported rotational alignment of the femoral and tibial components in TKA, axial mal-rotation with a tibiofemoral mismatch of more than 5 degrees is associated with increased risk of failure and poor clinical and functional outcomes [90-92]. Mal-rotation of the femoral or tibial components is traditionally considered a cardinal sin affecting patellar tracking and contributing to patellar subluxation, dislocation and patellofemoral pain [5]. However in modern orthopaedics, the advent of high quality polyethylene inserts and implant design have significantly decreased the observable functional/clinical deficits from rotational mal-alignment within limits [93].

2.4.8 Alignment in Coronal Plane:

Varus/valgus mal-alignment is the commonest cause of early loosening and is the most investigated alignment parameter after the overall alignment of the limb [62]. The coronal femoral component angle (cFCA) is the angle between the longitudinal axis of the femoral component and the mechanical axis of the femur in the coronal plane and every attempt is made not to exceed 8 degrees of valgus [62]. A good coronal femoral alignment is significantly associated with improved clinical and functional outcomes [90, 92]. The coronal tibial component angle (cTCA) is the angle between the longitudinal axis of the tibial component and the mechanical axis of the tibia in the coronal plane and every attempt is made to achieve 90 degrees [62]. A perfectly neutral (perpendicular) tibial component in the coronal plane is important in order to prevent early failure and produce good clinical outcome [90, 92].

2.4.9 Alignment in Sagittal Plane:

The component alignment in the sagittal plane is the least studied of all alignment parameters in determining outcome after TKA [6]. The radiographic parameters in the sagittal plane as ideally determined on a long leg, weighted, lateral x-ray include femoral component flexion/extension, tibial slope and posterior condylar offset (PCO) [94].

2.4.9.1 Femoral Component Angle:

The femoral component flexion/extension is determined by the sagittal femoral component angle (sFCA) as defined by the angle between the longitudinal axis of the femoral component and the mechanical axis of the femur in the sagittal plane as demonstrated in Fig 9 [94]. It is crucial to achieve an equidistant, symmetrical flexion/extension gap and even a small flexion of the femoral component leads to a reduction of the flexion gap severely limiting the range of motion causing early implant failure [95, 96]. To the researchers knowledge only two studies are published in the English language literature that investigated the influence of sagittal component alignment on implant survival and clinical outcome.

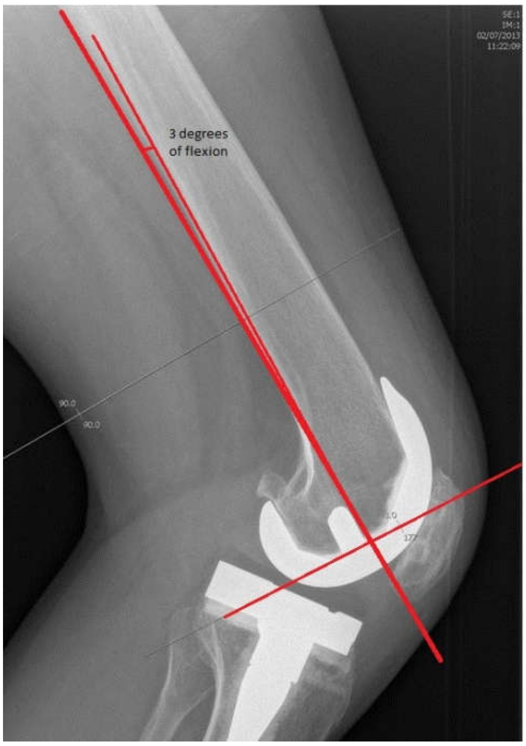


Fig 9: Femoral component angle in the sagittal plane (IMPAX, Agfa HealthCare Corporation, Greenville, SC, USA)

The earlier research by Faris et al investigated 623 knee replacements with the sagittal femoral component ranging from 20 degrees in extension to 20 degrees in flexion, but found no correlation with the ROM achieved [97]. The later research by Murphy et al investigated the effect of femoral component flexion on ROM (knee flexion and extension), outcome scores (WOMAC, SF-36), quadriceps strength, functional tests (timed stand test, SCT) and satisfaction [94]. A strong correlation between femoral component flexion, improved ROM and worsening scores for the mental component of SF-36 was observed [94].

2.4.9.2 Posterior Condylar Offset:

The PCO is defined as the maximal sagittal plane distance between the posterior femoral condyle and the posterior femoral cortex as demonstrated in Fig 10 [94, 98]. Malviya et al demonstrated that PCO is an important predictor of knee flexion [99]. In contrast, Bauer et al did not find any correlation between PCO and post-operative knee flexion [100]. Therefore, there is a clear need for further comprehensive investigation to determine the influence of PCO on clinical outcome measures particularly ROM.

Fig 10: Posterior condylar offset (IMPAX, Agfa HealthCare Corporation, Greenville, SC, USA)

2.4.9.3 Tibial slope:

Fig 11: Tibial slope in the sagittal plane (IMPAX, Agfa HealthCare Corporation, Greenville, SC, USA)

Tibial slope is the angle between the longitudinal axis of the tibial component and the mechanical axis of the tibia in the sagittal plane as demonstrated in Fig 11 [101]. An increase in tibial slope could limit extension and increase flexion and a decrease in tibial slope could result in laxity on extension and stiffness on flexion [6]. Increased tibial slope can improve knee flexion by facilitating posterior femoral rollback as a result of increased tension in posterior cruciate ligament [60]. Bellemans et al demonstrated an average gain of 1.7 degrees of flexion with every degree of increased posterior tibial slope [98]. Malviya et al also showed a positive correlation between tibial slope and ROM [99]. However, this is under scrutiny as recently, authors have demonstrated that an increased tibial slope failed to produce any significant improvement in ROM [100-102]. Therefore, the concept of an ideal tibial slope remains as elusive as that of an ideal sFCA and an ideal PCO.

CHAPTER 3 -

Hypothesis Development

The aim of this research project was to investigate the inter-relationship between the clinical outcomes as measured by the sagittal plane alignment of implant components, peri-operative kinematics, validated clinical rating systems, strength, balance and functional performance tests in patients at least one year post TKA at a regional academic hospital. This research project had a primary objective and two secondary objectives.

Although the relationship between alignment and clinical outcome has been extensively investigated, the role of sagittal component alignment, in particular the sFCA, PCO and tibial slope, has been poorly understood [94]. There is conflicting evidence about the influence of sFCA, PCO and tibial slope on ROM or flexion [94, 95, 97-99, 101]. Faris et al investigated 623 knee replacements with the sagittal femoral component ranging from 20 degrees in extension to 20 degrees in flexion, but found no correlation with the ROM achieved [97]. However, Murphy, et al investigated the effect of femoral component flexion on ROM (knee flexion and extension) and demonstrated a strong correlation [94]. Similarly, Malviya et al demonstrated that PCO is an important predictor of knee flexion and; Bauer et al did not find any correlation between PCO and post-operative knee flexion [99, 100]. Bellemans et al demonstrated an average gain of 1.7 degrees of flexion with every degree of increased posterior tibial slope [98]. Malviya et al also showed a positive correlation between tibial slope and ROM [99]. However, this is under scrutiny as recently, other researchers have demonstrated that an increased tibial slope failed to produce any significant improvement in ROM [100-102]. Hence, the relationship between sagittal plane component alignment as measured by sFCA, PCO and tibial slope and clinical outcome as measured by intra-operative kinematic data (MFA, MEA and ROM) currently lacks clarity. The primary objective of this research project was to determine the correlation between radiological sagittal plane alignment of the implant components, as defined by sFCA, PCO and tibial slope and the post-operative kinematics of the knee, as defined by MFA, MEA and ROM, in patients post CAS TKA. **Therefore, it was hypothesized (H1) that there will be a correlation between component alignment in the sagittal plane and intra-operative navigational kinematic data in patients post CAS TKA such that increased sFCA, PCO and tibial slope would increase the MFA and hence the ROM**.

Balance is a strong predictor of the quality of life and functional ability of patients post TKA [22]. Bascuas et al analysed the relationship between balance and clinical outcome measures; they demonstrated a statistically significant negative relationship between age and balance, despite their small sample size [18]. Corrigan et al demonstrated a significant correlation between hamstring to quadriceps ratio and balance in ACL deficient knees, suggesting a relatively greater correlation of flexion strength in comparison to extension strength with functional outcome in patients [103, 104]. However, Lee et al could not demonstrate a statistically significant correlation between hamstring strength and balance in patients with ACL deficient (Rho=0.239, p=0.506) and ACL intact (Rho=0.367, p=0.297) knees [105]. Schwartz et al demonstrated a statistically significant positive correlation between balance and TUG [22]. Hence, any possible relationship between balance and post-operative flexion strength, extension strength, range of motion or TUG currently lacks clarity. The first secondary objective of this research project was to determine the relationship between balance, as defined by Two Leg Eyes Open test, Two Leg Eyes Closed test and Single Leg Eyes Open test, and the clinical outcome measures, as defined by flexion strength, extension strength, ROM and TUG, in patients post TKA. **Therefore, it was hypothesized (H2) that there will be a correlation between balance and the clinical outcome measures such that improved strength would result in improved balance**.

Few clinical ratings systems such as OKS and KSS have been validated and considered broadly applicable across sex, age, activity level and implant type [14, 70]. While Laubenthal et al demonstrated that a minimum ROM of 90 degrees is required for activities of daily living, with higher-level activities like running and cycling dependent on increased ROM; Thomsen et al demonstrated no relationship between ROM and the ability to perform activities of daily living [15, 106]. Schwartz et al demonstrated a statistically significant positive correlation between balance and the Short Form -36 (SF-36) and Oxford Knee Score (OKS) [22]. Hence, any possible relationship between OKS and post-operative flexion strength, extension strength, ROM, balance, or TUG currently lacks clarity. The second secondary objective of this research project is to determine the correlation between subjective outcome measures, as defined by OKS and KSS, and objective outcome measures, as defined by flexion strength, extension strength, TUG, ROM and balance, in patients post TKA. **Therefore, it was hypothesized (H3) that there will be a correlation between subjective and objective outcome measures such that improved strength, ROM and balance would result in improved patient satisfaction**.

In summary, this research project is a significant addition to the current literature on outcome measures after TKA. The study design selected was a retrospective observational cohort study which enabled examination of the correlation between the outcome measures. The cohort refers to patients who have undergone CAS TKA at RBH from February 2009 to December

2012. A cohort study provided level III-2 evidence according to the NHMRC evidence hierarchy and adequately answered the research questions posed. A randomised controlled trial or quasi-randomised controlled trial will require intentional suboptimal alignment of components in subjects which would be unethical.

CHAPTER 4 -

Methodology

4.1 Study Design

This was a retrospective cohort study of 94 participants (105 knees) that underwent computer assisted (CAS) primary TKA between February 2009 and December 2012 at a single institution.

4.2 Patient Selection and Setting

Subjects were recruited from the Orthopaedics Outpatient Department at Rockhampton Base Hospital. Patients who returned for their regular follow-up appointment and met the inclusion criteria were invited to participate in the study. This clinic caters for most of the public patients in the wider Central Queensland catchment area requiring total joint arthroplasty. Referrals to this clinic are largely through General Practitioners working in Central Queensland. The average time from referral to be seen was six months and the average time on the waiting list for a joint replacement was six months. During this waiting period, subjects were encouraged to remain active and aim for a health body mass index. No referral to physiotherapy was initiated due to the nature of the project; however, if a subject elected to be treated by a private physiotherapist in the pre-operative interval, the treating surgeon did not discourage it. Regular analgesics for pain control was encouraged and supervised by the General Practitioner. All participants had been operated on by one of two experienced orthopaedic surgeons with a subspecialty interest in knee arthroplasty (EH and RK). Both surgeons work as full time consultant orthopaedic surgeons in a public hospital with over 25 years of operative experience.

4.3 Inclusion and Exclusion Criteria

The following inclusion criteria were used:

- Patients who have undergone CAS TKA at Rockhampton Base Hospital from February, 2009 to December, 2012.
- Minimum 1 year post TKA.
- Community ambulators at the time of data collection - in order to reduce the risk of falls and injury to participants.

The following exclusion criteria were used:

- Individual below the age of 40 years.

- Non osteoarthritic aetiology for joint degeneration
- People with an intellectual or mental impairment.
- Women who are pregnant and the human foetus.
- People highly dependent on medical care.
- Past medical history of connective tissue disorders such as Ehlers Danlos, Marfan's, etc.

4.4 Surgery, Post-surgical Care and Follow-up

The medial para-patellar approach was utilized for all cases as demonstrated in Fig 7. In addition, two 4.5 mm pins were placed into the distal femur and proximal tibia to attach trackers for the navigation system (Stryker OrthoMap Precision Knee Navigation System). All patients received a posterior cruciate retaining implant (Stryker Triathlon Total Knee Replacement System).

Both surgeons utilized standard pre- and post-operative protocols to minimize confounders in the study. Post-operatively patients were mobilized on day one by the physiotherapist, active ROM was encouraged and continuous passive motion machines were used. Patients were discharged when the following discharge criteria were met: active pain-free ROM 0-90 degrees; satisfactory wound healing; safe independent mobilisation; and no post-operative complications.

All patients were instructed to attend routine follow-up appointments at six weeks, three months, six months, one year, and annually thereafter.

4.5 Sample Size

A sample size calculation was performed. The calculation was designed to provide the number of cases required to discover a statistically significant ($p = 0.05$) correlation for a maximum of five co-variates with a medium effect size ($f^2 = 0.15$). The sample size calculation based on these parameters indicated that 91 patients were needed to provide a statistical power of 80%. Therefore, taking into account a 10% participant attrition/drop-out rate, it is the intention of the researcher to recruit at least 100 participants.

4.6 Variables

The following outcome measures were used: kinematic variables (pre-, intra- and post-operative measurements for MFA, MEA and ROM); sagittal plane alignment of implant components (sFCA, PCO, tibial slope); clinical rating systems (OKS and KSS); isometric strength (knee flexion and extension); balance (two legs eyes open – TLEO; two legs eyes closed – TLEC; single leg eyes open – SLEO); and TUG. The navigational computer database was used to develop the list of potential participant. The navigational kinematic data of potential participants was then extracted.

4.6.1 Kinematic Data

- Pre-operative kinematics: navigational data extracted
    - MFA – the maximum knee flexion acquired during passive flexion of the knee by the surgeon post administration of anaesthesia and prior to commencement of surgery as registered by the navigational computer.
    - MEA - the maximum knee extension acquired during passive extension of the knee by the surgeon post administration of anaesthesia and prior to commencement of surgery as registered by the navigational computer.
    - ROM – the range of motion during passive flexion-extension of the knee by the surgeon post administration of anaesthesia and prior to commencement of surgery as registered by the navigational computer.
- Intra-operative kinematics: navigational data extracted
    - MFA – the maximum knee flexion acquired during passive flexion of the knee by the surgeon post implant in situ as registered by the navigational computer.
    - MEA - the maximum knee extension acquired during passive extension of the knee by the surgeon post implant in situ as registered by the navigational computer.
    - ROM – the range of motion during passive flexion-extension of the knee by the surgeon post implant in situ as registered by the navigational computer.

- Post-operative kinematics: measured using the Baseline SS 180 Degree Robinson Goniometer (6 inch) during the one-year follow-up review at the orthopaedic outpatients department. Patients were instructed to lie supine on the examination bed and advised to relax all muscles such that the investigator could freely manipulate the knee. The goniometer was centred on lateral aspect of the knee joint line with one arm placed along the long axis of the femur pointing to the greater trochanter and the other arm placed along the long axis of the tibia pointing to the lateral malleolus.
    - MFA – the maximum knee flexion acquired during passive flexion of the knee by the investigator as measured using a goniometer at least one year post surgery.
    - MEA - the maximum knee extension acquired during passive extension of the knee by the investigator as measured using a goniometer at least one year post surgery.
    - ROM – the range of motion during passive flexion-extension of the knee by the investigator as measured using a goniometer at least one year post surgery.

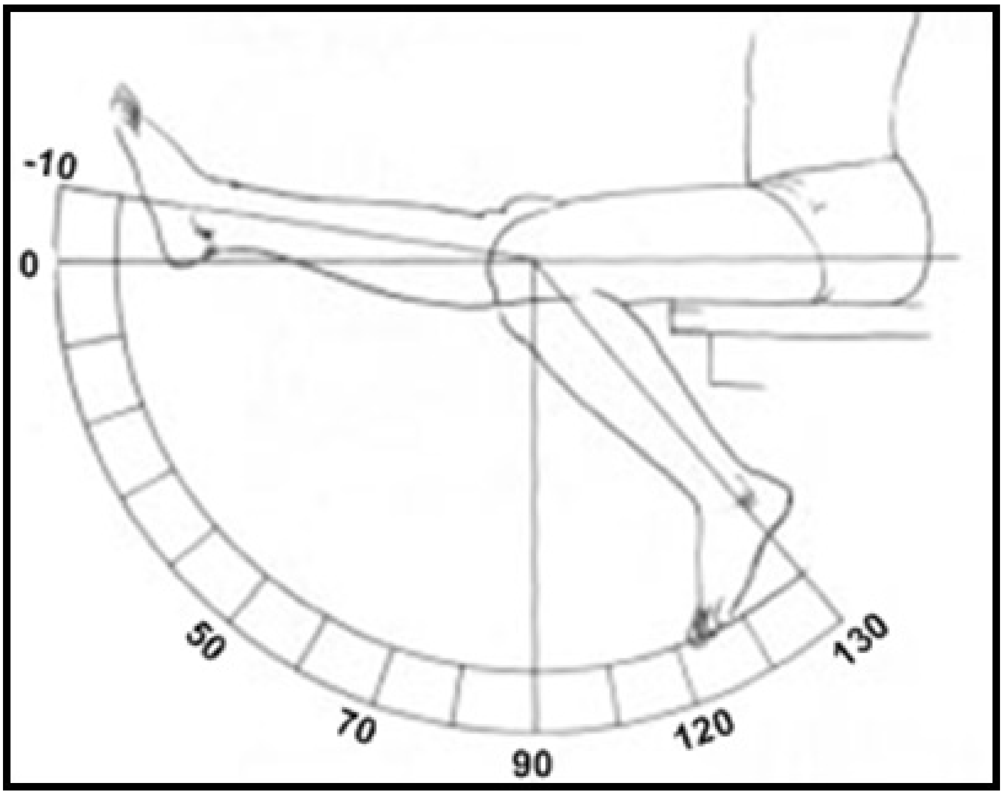


Fig 12: Post-operative measurement of MEA, MFA and ROM using goniometer [63]

Lustig et al demonstrated that CAS TKA is a validated tool for measurement of kinematic data with an accuracy of +/- 1 degree [107]. Angles obtained in flexion were noted as positive (+) and angles obtained in extension were noted as negative (-). All three kinematic parameters were recorded to the nearest whole number.

4.6.2 Sagittal Plane Component Alignment

The primary researcher accessed IMPAX (Agfa HealthCare Corporation, Greenville, SC, USA), the digital radiographic database at RBH, to measure on pre-existing true lateral weight-bearing radiographs the sagittal plane component alignment. True lateral radiographs as defined by superimposition of posterior condyles of the femoral implant component, were taken on post-operative day one by a single, senior radiographer to a pre-established protocol. Repeat imaging was performed until true lateral radiographs were obtained.

Fig 13A Fig 13B Fig 13C

Fig 13 – A true lateral knee X-ray demonstrating: A - a sagittal femoral component angle of 1.8 degrees in extension; B – a posterior condylar offset of 29.7mm; C – a tibial slope of 2.6 degrees in flexion *(*IMPAX, Agfa HealthCare Corporation, Greenville, SC, USA)

- sFCA - the angle between the longitudinal axis of the femoral component and a line along the distal 15cm of the posterior femoral cortex that was parallel to the anatomical femoral axis as demonstrated in Fig 13A.

- PCO - maximal sagittal plane distance between the posterior femoral condyle and the posterior femoral cortex as demonstrated in Fig 13B.

- Tibial slope - the angle between the longitudinal axis of the tibial component and a line along the proximal 15cm of the posterior tibial cortex that was parallel to the anatomical axis of the tibia as demonstrated in Fig 13C.

All three alignment parameters were recorded with an accuracy of one decimal place.

When patients attended their regular post-operative follow-up clinic at the Orthopaedics Outpatients Department, the following clinical outcome measures were recorded:

4.6.3 Clinical Rating Systems

The Clinical Rating Systems used for this study were:

- OKS - Participants were asked to complete the questionnaire to best reflect the outcome of the operated knee in the last 4 weeks. The Oxford Knee Score consists of twelve items, each with a score of one to four (from worst to best): pain; difficulty washing and drying self; difficulty getting in and out the car/public transport; walking duration; pain on standing; limp; ability to kneel; night pain; interference with work; giving way; ability to do shopping and ability to descend stairs. A total score out of 48 was then obtained.
- KSS – The researcher then completed the questionnaire in consultation with the participant. The Knee Society Clinical Rating System categorises subjects to identify those subjects whose function may be undermined by factors other than the knee in question:

  A: No substantial disease in the contralateral knee

  B: Substantial arthrosis

  C: Multiple joint involvement or generalised disability

  It then assessed subjects by two scores: the Knee score and the Function score. The Knee score is comprised of pain (50 points), range of motion (25 points with a maximum of 125 degrees) and stability, measuring antero-posterior and mediolateral stability separately (25 points). Deductions are made for flexion contracture, extension lag, and alignment. The Function score comprised of walking distance (50 points), and stair climbing (50 points) with deductions for using a walking aid. The clinical examination component of the KSS was performed by the principal investigator (JA) who was experienced in orthopaedic examination:

- Range of motion (ROM): ROM was measured using a goniometer on the lateral aspect of knee from full passive extension to full passive flexion. The centre of the goniometer was placed at the tibiofemoral articulation, with one arm following the line of the femur and the other following the line of the tibia.
- Antero-posterior displacement: The investigator massaged the subject's hamstrings to help in relaxation, and then sat on the foot with the subject's permission with the knee flexed at 90°. The investigator then drew the tibia anteriorly on the femur and estimated this displacement to the nearest whole number in millimeters (mm). Similar posterior displacement of the tibia on the femur was estimated using the same methodology.
- Mediolateral displacement: The subjects' lower limb was held under the investigator's axilla and supported with one hand while the other hand applied valgus and varus stress to the knee at 30 degrees of knee flexion. The angle formed in the coronal plane between the femur and tibia was estimated in degrees to the nearest whole number and added to correlate to a score.
- Flexion contracture: The subject was asked to straighten both knees flat on the bed, and passive extension or the lack thereof was measured on the operated leg with the goniometer.
- Extension lag: If full extension was not achieved actively, the investigator gently passively extended the affected knee. The difference between active and passive extension was measured in degrees and correlated to a score.
- Alignment: The angle between a line between the anterior superior iliac spine and the centre of the patella and a line between the centre of the patella and the centre of the ankle will be measured in degrees and correlated to a score.

4.6.4 Strength

The use of Nintendo Wii platform as a novel, cheap, accurate and reproducible measure of force was previously validated by Bartlett et al [108]. Notably, by using the Nintendo Wii platform, measurement error due to variations and limitations in tester's strength was eliminated. Participants were asked to sit on a comfortable chair with Velcro strapping placed across the waist and chest to stabilize the torso and to push against the Nintendo Wii platform with their foot to prevent recruitment of upper body strength. Isometric strength was defined as the maximum force obtained as measured in Newton (N). The maximal volitional isometric contraction force applied on the Nintendo Wii platform provided an objective measure of isometric strength at 90 degrees of knee flexion. As the knees were tested in 90 degrees of flexion, it allowed for elimination of compensation for gravity. Measurement of strength was performed as demonstrated in Fig 14:

- Extension Strength – the Nintendo Wii platform was placed in front of the participant's foot. Participants were asked to push against the platform with the front of the foot (operated knee) as hard as they could over five seconds and then to relax. This was repeated three times and the best score noted.
- Flexion Strength - the Nintendo Wii platform was placed behind the participant's foot. Participants were asked to push against the platform with the heel of the foot (operated knee) as hard as they could over five seconds and then to relax. This was repeated three times and the best score noted.

Fig 14: Assessment of extension and flexion strength using Nintendo Wii Platform

The use of three attempts allowed for elimination of sub-maximal measurements due to suboptimal effort and exhaustion. Additional measurements were taken if the patients reported a failure to achieve a maximum effort. Participants were allowed 2 mins rest between each attempt and 5 mins rest between the standardized progression for all participants from extension to flexion strength measurement. The peak torque measurements were normalized to body weight that facilitated reliable comparisons of strength data across the cohort.

4.6.5 Balance

The use of Nintendo Wii platform as an inexpensive, highly accurate, and reproducible measure of centre of pressure (CoP) displacement or balance was validated by Clark et al and the described protocol was used to measure balance [109]. The Nintendo Wii platform, which has a useable surface of 45 cm x 26.5 cm, was able to calculate the amount of sway thus delivering an objective measure of balance. Participants were instructed to stand on the platform with their hands placed on their hips or by their side, looking straight ahead fixed at an imaginary point and to minimize the amount of sway by remaining as still as possible for the duration of the trial as demonstrated in Fig 15. Three balance tasks were used based on their varying difficulty and common use in literature:

- Two Legs Eyes Open – the right foot on the right pedal, the left foot on the left pedal and eyes open, the amount of sway was assessed for one minute.
- Two Legs Eyes Closed – the right foot on the right pedal, the left foot on the left pedal and eyes closed, the amount of sway was assessed for one minute.
- Single Leg Eyes Open – the foot of the operated knee on the centre of the platform, the foot of the non-operated knee slightly raised off the platform, the amount of sway was assessed for ten seconds.

Fig 14A Fig 14B

Fig 15: Assessment of balance (centre of pressure displacement – path velocity) using Nintendo Wii Platform. A – Two Legs Eyes Open/Closed with the right foot on the right pedal, the left foot on the left pedal. B – Single Leg Eyes Open with the foot of the operated knee on the centre of the platform and the foot of the non-operated knee slightly raised off the platform.

The Nintendo Wii platform was interfaced with a laptop computer (operating on Microsoft Windows 7) using the same C++ custom-written software (Labview 8.5 National Instruments, Austin, TX, U.S.A) validated by Clark et al and a bluetooth connection. The platform was calibrated by placing a variety of known loads at different positions that has been shown to greatly improve the measurement reliability and reduce measurement errors using the protocol described by Clark et al [109]. Participants were given three attempts at each balance task to allow for elimination of sub-maximal measurements due to suboptimal effort and exhaustion. The data obtained was automatically recorded in a secure folder on the laptop and the best performance as measured by the total centre of pressure path velocity (cm/sec) was extracted for data analysis. Additional measurements were taken if the patients reported a failure to achieve a maximum performance. Participants were allowed 2 mins rest between each attempt and 5 mins rest between each balance task. All trials were completed with participants wearing their regular footwear and the order of progression was standardized for all patients.

4.6.6 TUG

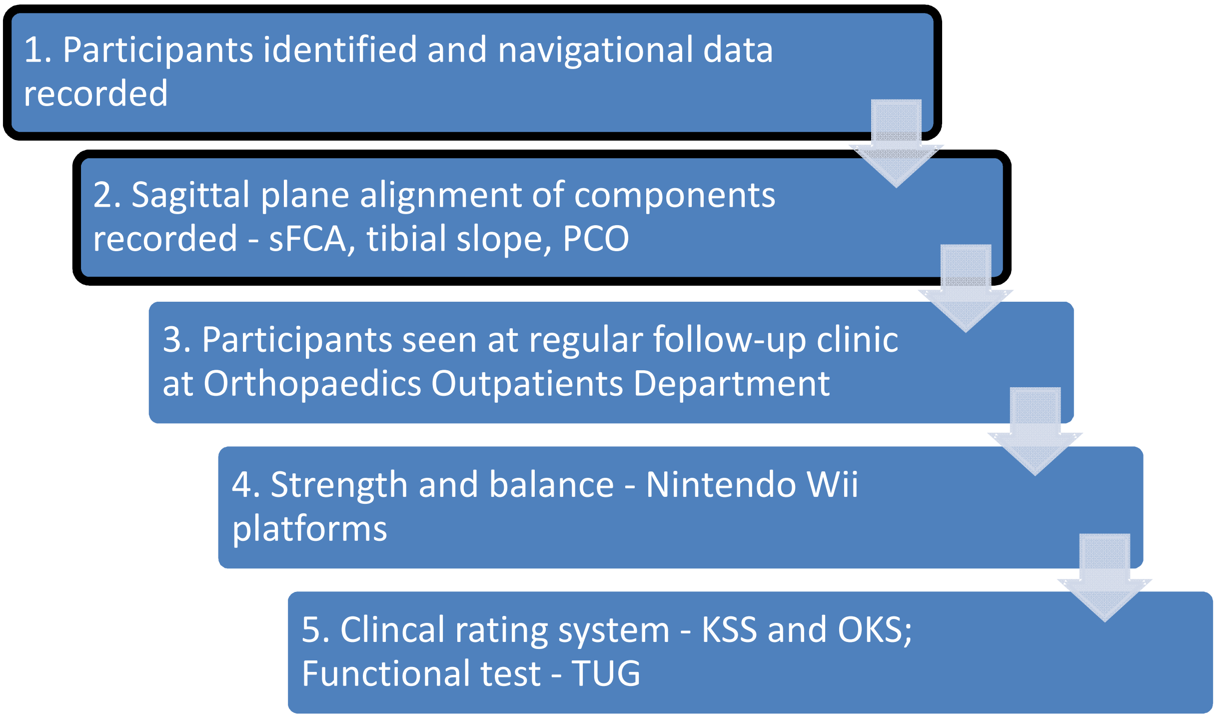
For the “timed up and go test” (TUG), the protocol utilised by Bade et al was used for this project, and was defined as the time taken to perform the test in seconds (sec) [20]. TUG has excellent test-retest reliability. Participants were asked to sit on a comfortable chair with their feet planted on the ground behind the starting line.

- Standard TUG - upon prompting, participants are required to stand up, walk 3 meters, turn around, walk back and sit back down.
- Counting TUG - upon prompting, participants are required to perform the standard TUG while counting backwards from a randomly allotted number between 20 and 100, out loud so it can be heard by the investigator.
- Water TUG - upon prompting, participants are required to perform the standard TUG while carrying a cup with water full to 1 cm below the brim.

Participants were permitted and encouraged to use the arms of the chair for support during rising and sitting if needed to reduce risk of falls and injury. Participants were given an attempt to warm-up and establish the baseline. Participants were then encouraged to perform better than their baseline. The peak performance after three attempts at each task was noted. Additional attempts were permitted if the patients reported a failure to achieve a maximum performance. Participants were allowed 2 mins rest between each attempt and 5 mins rest between each TUG task. All trials were completed with participants wearing their regular footwear and walking aids with a standardized order of progression for all patients. Time was recorded to the nearest 0.1 sec.

These tests provide a comprehensive evaluation of the participant's clinical improvement after total knee arthroplasty. After this phase of data collection, participant information was de-identified. The data collection process is summarized in Figure 16.

Figure 16: Summary of data collection process.



4.7 Data Analysis

A pilot study of 20 patients with three observers and three repeated measurements was performed to determine the inter- and intra-observer reliability for measurement of alignment parameters. Means, standard deviations and 95% confidence intervals of the alignment parameters, kinematic data, outcome scores, balance, strength and TUG was calculated.

H1: States that there will be a correlation between component alignment in the sagittal plane and intra-operative navigational kinematic data in patients post CAS TKA. There are three radiographical variables (sFCA, PCO and tibial slope) and three intra-operative kinematic variables (MFA, MEA and ROM). Data was analysed using three multiple linear regression models:

- MFA (dependent variable) – sFCA, PCP and Tibial slope (independent variables)
- MEA (dependent variable) – sFCA, PCP and Tibial slope (independent variables)

- ROM (dependent variable) – sFCA, PCP and Tibial slope (independent variables)

H2: States that there will be a correlation between balance and the clinical outcome measures in patients post TKA. There are three balance variables (Two Legs Eyes Open, Two Legs Eyes Closed and Single Leg Eyes Open) and five clinical outcome measures (flexion strength, extension strength, intra-operative ROM, TUG and KSS). Data was analysed using three multiple linear regression models followed by calculation of relative importance metrics for statistically significant models:

- Two Legs Eyes Open (dependent variable) - flexion strength, extension strength, post-operative ROM and TUG (independent variables)
- Two Legs Eyes Closed (dependent variable) - flexion strength, extension strength, post-operative ROM and TUG (independent variables)
- Single Leg Eyes Open (dependent variable) - flexion strength, extension strength, post-operative ROM and TUG (independent variables)

H3: States that there will be a correlation between subjective and objective outcome measures in patients post TKA. There are two subjective outcome measures (OKS and KSS) and five objective outcome measures (flexion strength, extension strength, post-operative ROM, TUG and balance). If the Pearson product-moment correlation coefficient between OKS and KSS is greater than or equal to 0.7, then data was analysed using one multiple linear regression with OKS as the independent variable followed by calculation of relative importance metrics. Otherwise, data was analysed using two linear regressions:

- OKS (dependent variable) – flexion strength, extension strength, post-operative ROM, TUG and balance (independent variables)
- KSS (dependent variable) – flexion strength, extension strength, post-operative ROM, TUG and balance (independent variables)

A p-value less than 0.05, was considered statistically significant. All analyses was conducted using STATA SE (Version 12.0 ; StataCorp, College Station, Texas, USA) for Windows.

4.8 Ethics Application

Ethical clearance was sought from the Central Queensland Human Research Ethics Committee as this research is to be conducted within a Queensland Health facility i.e. Rockhampton Base Hospital. An expedited ethical clearance was also sought from the University of Queensland Human Research Ethics Committee as the principal researcher is undertaking this research project as part of his proposed Doctor of Philosophy at the University of Queensland. Ethical clearance was obtained from both these ethics committees (Central Queensland - HREC/12/QCQ/21; School of Medicine – 2012-SOMILRE-0056).

4.9 Citation Style

The citation style used is consistent with the publication target: Journal of Arthroplasty.

CHAPTER 5 -

Results

5.1 Descriptive Analysis

Excellent inter- and intra-rater reliability (intra-class correlation coefficient, 0.956 and 0.938 respectively) was noted in the pilot study of 20 patients. Hence, the variables were subsequently measured for all patients by a single observer. 11 (nine females and two males) of the 94 participants had bilateral TKA resulting in a total of 105 knees with an even site distribution of 53 left knees and 52 right knees. The descriptive analysis of measured variables with subset analysis based on gender can be noted in Table 1.0. The mean age of participants was 70.8 years (SD=8.3) and those with bilateral (μ=73.9, SD=5.4) TKA were older than those with unilateral (μ=69.5, SD=9.0) TKA (t (51.57) =2.33, $p<0.05$). There was a female preponderance with 60 females (33 left and 27 right) and 45 males (20 left and 25 right).

Table 1.0 – Descriptive analysis of measured variables: Five number summary and standard deviation of mean

Variable	Gender	Min	1Q	Median	Mean	Std Dev	3Q	Max
Descriptive								
Age (years)	Male	56.83	68.93	71.75	72.10	6.70	75.92	84.47
	Female	42.41	67.10	70.50	69.96	9.22	77.34	81.99
	Total	42.41	67.36	71.01	70.81	8.31	77.34	84.47
Alignment								
Femoral Component Angle (degree)	Male	-9.10	-2.20	0.50	0.18	3.99	2.50	9.80
	Female	-8.90	-3.30	-0.90	-0.76	4.00	1.53	13.50
	Total	-9.10	-3.00	-0.40	-0.36	4.00	1.90	13.50
Posterior Condylar Offset (degree)	Male	17.40	29.45	32.00	31.39	4.20	33.70	40.60
	Female	22.40	29.45	31.95	31.82	3.59	33.80	39.70
	Total	17.40	29.45	32.00	31.63	4.20	33.70	40.60
Tibial Slope (degree)	Male	-4.00	-0.80	1.40	0.99	2.26	2.30	5.40
	Female	-4.00	-0.80	0.65	0.76	2.48	2.00	7.80
	Total	-4.00	-0.80	1.10	0.86	2.38	2.00	7.80

Strength								
Extension Strength (Newton)	Male	8.30	29.90	40.50	40.71	17.70	53.90	92.50
	Female	8.40	18.50	22.10	24.38	9.02	30.52	50.20
	Total	8.30	20.30	27.90	31.38	15.64	40.50	92.50
Flexion Strength (Newton)	Male	4.10	8.40	10.70	11.52	4.97	12.90	29.70
	Female	2.10	5.38	7.95	8.53	4.31	10.50	26.00
	Total	2.10	7.00	9.00	9.81	4.82	11.60	29.70
Function								
Timed Up and Go (seconds)	Male	6.00	7.35	7.79	9.02	3.51	8.47	21.47
	Female	6.69	8.41	9.63	10.53	3.43	11.07	23.80
	Total	6.00	7.65	8.88	9.89	3.53	10.68	23.80
Kinematics								
Pre-MEA (degree)	Male	-6.00	1.00	4.50	5.20	6.23	9.00	19.50
	Female	-7.50	0.25	4.50	6.44	8.00	12.00	29.50
	Total	-7.50	0.50	4.50	5.90	7.28	10.63	29.50
Pre-MFA (degree)	Male	88.50	110.0	117.50	116.20	10.52	123.50	133.00
	Female	87.00	98.50	113.50	109.90	11.45	117.00	137.00
	Total	87.00	104.40	114.80	112.60	11.43	120.50	137.00
Pre-ROM (degree)	Male	76.00	104.00	113.00	111.00	13.00	118.50	137.00
	Female	66.50	93.50	104.00	103.50	15.05	115.20	136.50
	Total	66.50	96.38	108.00	106.72	14.61	117.00	137.00
Intra-MEA (degree)	Male	-4.00	-1.38	0.00	0.67	3.44	1.38	11.50
	Female	-38.00	-1.75	0.00	-1.14	6.22	1.00	8.00
	Total	-38.00	-1.50	0.00	-0.39	5.30	1.00	11.50
Intra-MFA (degree)	Male	73.00	106.10	115.50	113.40	13.72	122.50	136.50
	Female	80.00	103.80	114.00	112.60	12.74	123.00	138.50
	Total	73.00	104.50	115.00	112.90	13.10	123.00	138.50
Intra-ROM (degree)	Male	76.50	107.20	115.00	112.80	13.77	122.40	136.00
	Female	89.00	102.50	114.00	113.70	13.33	123.50	147.50
	Total	76.50	103.50	114.50	113.30	13.45	123.50	147.50

Post-MEA (degree)	Male	-5.00	0.00	0.00	1.89	3.58	5.00	15.00
	Female	-5.00	0.00	0.00	2.00	3.71	5.00	10.00
	Total	-5.00	0.00	0.00	1.95	3.64	5.00	15.00
Post-MFA (degree)	Male	70.00	100.00	110.00	108.40	12.73	120.00	130.00
	Female	50.00	98.75	105.00	103.20	11.23	110.00	120.00
	Total	50.00	100.00	105.00	105.40	12.11	110.00	130.00
Post-ROM (degree)	Male	60.00	100.00	110.00	106.50	14.82	115.00	130.00
	Female	40.00	95.00	105.00	101.20	12.74	110.00	120.00
	Total	40.00	95.00	105.00	103.50	13.85	110.00	130.00
Balance								
Path Velocity – TLEO (cm/sec)	Male	0.68	0.96	1.31	1.46	0.72	1.65	3.89
	Female	0.61	0.92	1.04	1.30	0.75	1.47	5.66
	Total	0.61	0.93	1.14	1.37	0.74	1.59	5.66
Path Velocity – TLEC (cm/sec)	Male	0.95	1.39	1.97	2.22	1.02	3.00	4.96
	Female	0.85	1.35	1.66	1.95	1.04	2.13	6.26
	Total	0.85	1.35	1.73	2.07	1.03	2.58	6.26
Path Velocity – SLEO (cm/sec)	Male	2.05	4.61	5.46	5.81	2.23	6.70	11.59
	Female	0.86	4.06	4.62	4.70	1.61	5.43	10.36
	Total	0.86	4.14	4.93	5.23	2.00	5.90	11.59
Clinical Rating Systems								
Oxford Knee Score	Male	20.00	34.00	43.00	39.33	8.29	46.00	48.00
	Female	18.00	33.75	40.00	37.75	7.64	44.00	48.00
	Total	18.00	34.00	41.00	38.43	7.92	44.00	48.00
Knee Society Score	Male	33.00	66.00	79.00	74.57	13.50	85.00	90.00
	Female	26.00	67.00	78.00	73.87	14.79	84.25	89.00
	Total	26.00	67.00	78.00	74.17	14.19	85.00	90.00

Table 2.0 – Difference in measured variables between male-female, right-left and unilateral-bilateral (delta value; 95% confidence interval; p-value)

	Male versus Female	Right versus Left	Unilateral versus Bilateral
Descriptive			
Age (years)	2.14; -1.98-6.26; p=0.30	-0.32; -4.72-4.09; p=0.89	**-4.39; -8.17--0.60; p<0.001**
Alignment			
Femoral Component Angle (degree)	0.94; -0.63-2.50; p=0.24	0.45; -1.10-2.00; p=0.57	**2.39; 0.50-4.27; p=0.01**
Posterior Condylar Offset (degree)	-0.43; -2.16-1.30; p=0.62	-1.07; -2.70-0.56; p=0.20	**2.50; 0.59-4.40; p=0.01**
Tibial Slope (degree)	0.23; -0.69-1.15; p=0.62	-0.53; -1.44-0.39; p=0.26	-0.01; -1.05-1.03; p=0.99
Strength			
Extension Strength (N)	**16.34; 10.57-22.10; p<0.001**	**6.15; 0.16-12.13; p<0.001**	2.24; -3.29-7.76; p=0.42
Flexion Strength (N)	**2.99; 1.15-4.83; p<0.001**	1.71; -0.15-3.56; p=0.07	0.03; -2.66-2.72; p=0.98
Function			
Timed Up and Go (sec)	**-1.51; -2.87--0.15; p<0.001**	0.29; -1.09-1.66; p=0.68	**1.21; 0.24-2.17; p<0.001**
Kinematics			
Maximum Extension Angle (degree)	-0.11; -1.53-1.31; p=0.88	-0.25; -1.66-1.16; p=0.73	1.03; -0.53-2.59; p=0.19
Maximum Flexion Angle (degree)	**5.14; 0.38-9.87; p=0.03**	1.29; -3.41-5.98; p=0.59	2.30; -1.93-6.52; p=0.28
Range of Motion (degree)	5.24; -0.24-10.72; p=0.06	1.53; -3.84-6.90; p=0.57	1.26; -3.74-6.26; p=0.62
Balance			
Path Velocity – TLEO (cm/sec)	0.17; -0.13-0.46; p=0.28	0.04; -0.26-0.33; p=0.82	0.22; -0.04-0.47; p=0.10

Path Velocity – TLEC (cm/sec)	0.27; -0.14-0.68; p=0.19	0.03; -0.38-0.44; p=0.87	-0.01; -0.52-0.51; p=0.98
Path Velocity – SLEO (cm/sec)	**1.11; 0.29-1.93; p<0.001**	**0.86; 0.03-1.68; p<0.001**	0.37; -0.37-1.11; p=0.32
Clinical Rating Systems			
Oxford Knee Score	1.59; -1.55-4.72; p=0.32	-0.24; -3.32-2.84;p=0.88	**-4.52; -7.02--2.02; p<0.05**
Knee Society Score	0.70; -4.81-6.21; p=0.80	-2.26; -7.77-3.26; p=0.42	**-6.81; -11.76--1.85; p<0.05**

5.2 Hypothesis 1

Alignment parameters, sFCA, PCO and tibial slope, were used in a regression analysis to predict kinematics, MFA, MEA and ROM. The prediction model for MFA was statistically significant (p=0.03) and accounted for 8.4% of the variance. Both FCA (R^2=0.3, p=0.01) and PCO (R^2=0.2, p=0.05) are statistically significant weak predictors of MFA as noted in Fig 17. The prediction model for ROM did not achieve statistical significance, but accounted for 6.5% of the variance. FCA (R^2=0.2, p=0.02) was a statistically significant weak predictor of ROM as noted in Fig 17. The prediction model for MEA was not statistically significant (p=0.38) and accounted for only 3.0% of the variance.

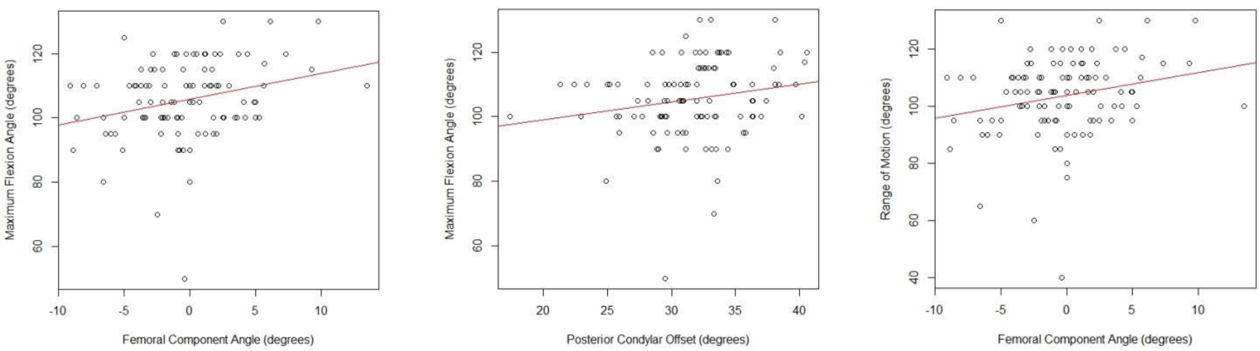
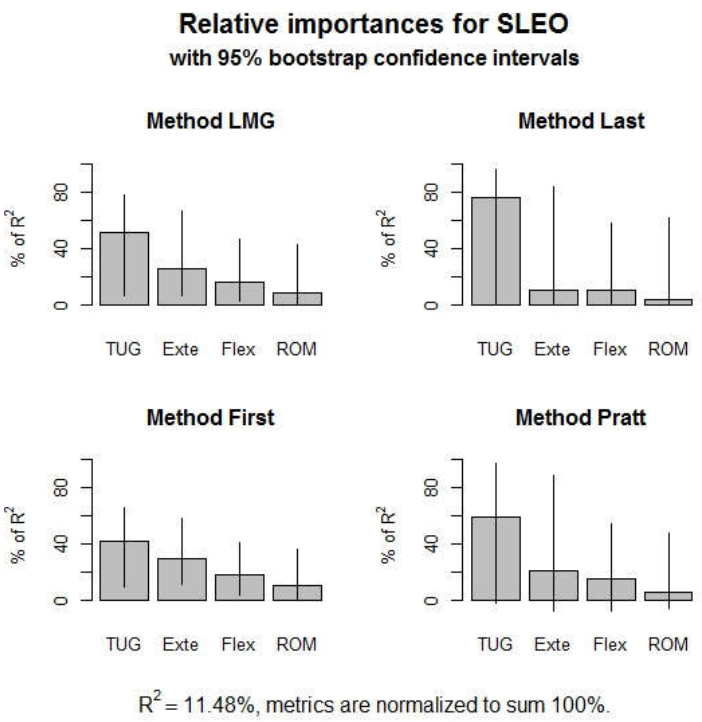


Fig 17: Femoral Component Angle (FCA) and Posterior Condylar Offset (PCO) were statistically significant predictors of Maximum Flexion Angle (MFA); Femoral Component Angle was also a statistically significant predictor of Range of Motion (ROM).

5.3 Hypothesis 2

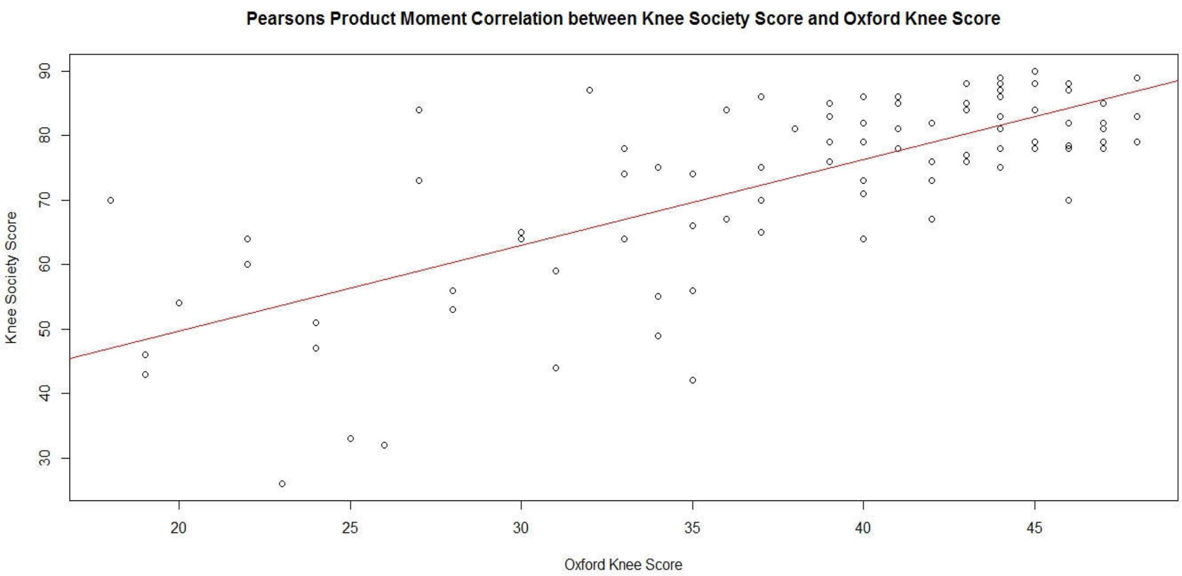
Fig18: Relative importance of predictors for SLEO with 95% bootstrap confidence intervals



Extension strength, flexion strength, ROM, and TUG were used in a regression analysis to predict balance using SLEO. The prediction model was statistically significant, F (4, 100) = 3.24, p=0.02, and accounted for 11.5% of the variance of SLEO. TUG was the only statistically significant predictor (R^2=0.22, p=0.05) of SLEO as demonstrated in Fig 18. Regression analyses were also performed to predict TLEO and TLEC from extension strength, flexion strength, ROM, and TUG. However, these models did not achieve statistical significance and accounted for very little of the variance, F (4, 100) = 1.23, R^2=0.05, p=0.30 and F (4, 100) = 1.02, R^2=0.04, p=0.40, respectively. Flexion strength contributed most to balance with TLEO (R^2=-0.20, p=0.09) and TLEC (R^2=-0.22, p=0.06), but did not achieve statistical significance.

5.4 Hypothesis 3

Fig 19: Pearson's product moment correlation between Knee Society Score and Oxford Knee Score.



There was a statistically significant positive correlation between Oxford Knee Score and Knee Society Score (r = 0.74, p=0.001) as demonstrated in Fig 19. Therefore, extension strength, flexion strength, balance, ROM, and TUG were used in a regression analysis to predict OKS. The prediction model was statistically significant, F (7, 80) = 6.19, p=0.001, and accounted for 35.15% of the variance of OKS. ROM (R^2=0.34, p=0.02) and TUG (R^2=-0.40, p=0.001) were found to be statistically significant predictors of OKS as demonstrated in Fig 20 and Fig 21.

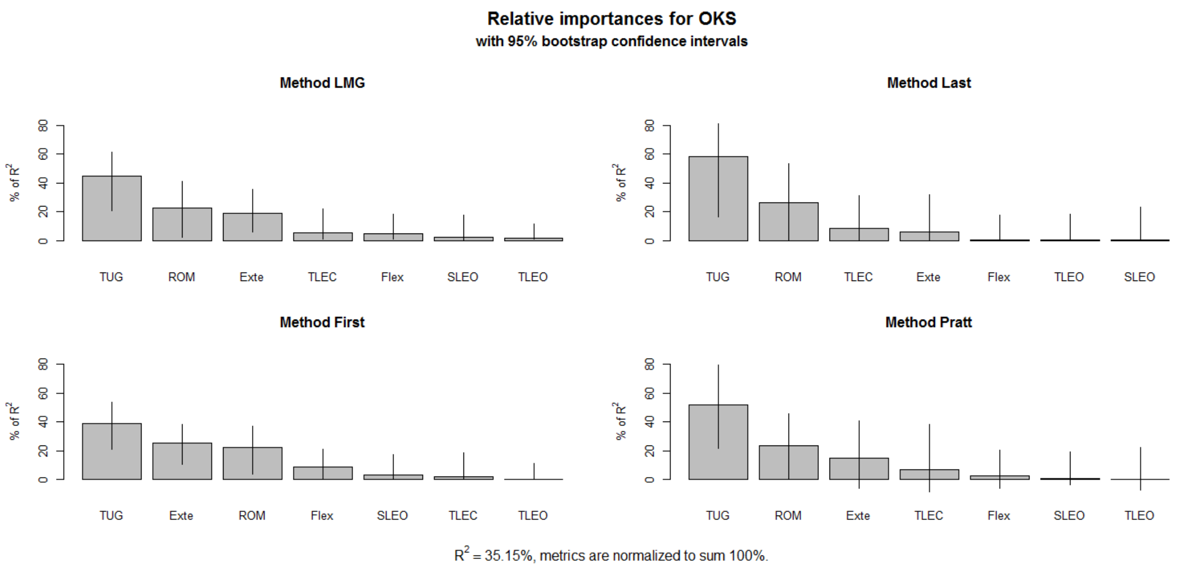
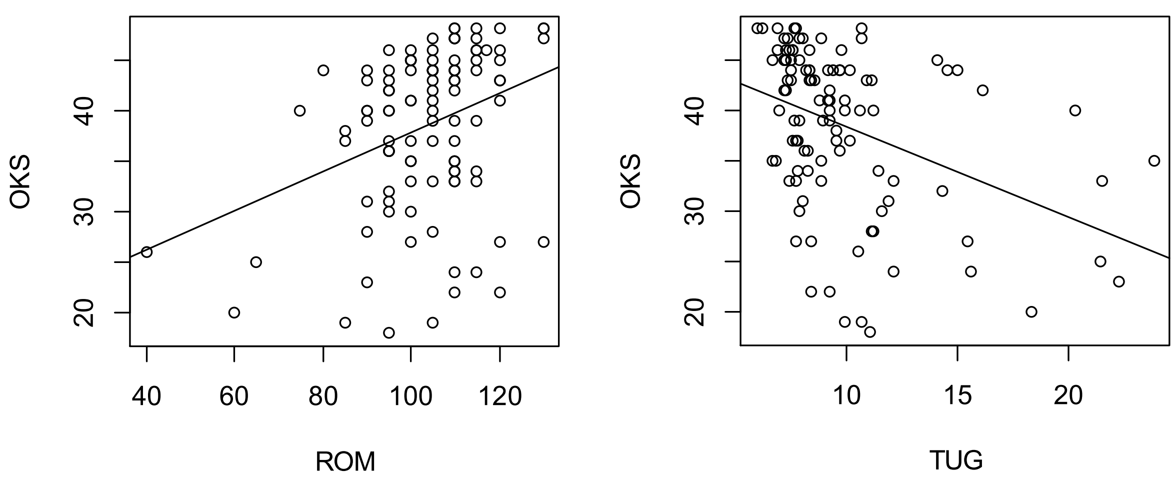


Fig20: Relative importance of predictors for Oxford Knee Score with 95% bootstrap confidence intervals.

However, flexion strength (R^2=0.16, p=0.75), extension strength (R^2=0.29, p=0.26), and balance as measured with TLEO (R^2=0.01, p=0.79), TLEC (R^2=0.16, p=0.19) and SLEO (R^2=0.13, p=0.85) did not achieve statistical significance.

Fig 21: Range of motion and Timed Up and Go were statistically significant predictors of Oxford Knee Score.



CHAPTER 6 -

Discussion

6.1 Hypothesis 1

The most important findings of this study are that the femoral component angle (FCA) was a statistically significant predictor of maximum flexion angle (MFA) and range of motion (ROM) and that the posterior condylar offset (PCO) was a statistically significant predictor of MFA. However, tibial slope (TS) does not contribute significantly to knee kinematics after TKA. With significant improvements in implant design and survival, patients are increasingly concerned about objective functional outcomes such as knee kinematics to evaluate the success of their total knee arthroplasty (TKA) [1]. The influence of sagittal plane component alignment, particularly the femoral component angle (FCA), tibial slope (TS) and posterior condylar offset (PCO) on knee kinematics is contentious.

Most surgeons aim to place the femoral component in neutral alignment to the femoral axis in the sagittal plane [110]. The FCA was a statistically significant predictor of MFA and ROM in patients with osteoarthritis who underwent primary TKA using a posterior cruciate retaining implant. Although statistically significant, FCA was a weak predictor for MFA (one degree increase in FCA, increased the MFA by 0.3 degrees) and ROM (one degree increase in FCA, increased the ROM by 0.2 degrees). This is similar to the finding in a recent study that flexing the femoral implant in cruciate retaining TKA provides an immediate increase in knee flexion [94]. The increase in flexion could be secondary to the increase in the PCO derived from flexing the femoral component. However, these findings are in contrast with an earlier study that demonstrated no correlation between implant position and knee range of motion [97]. This could be due to the retrospective nature of their study and the use of non-standardized radiographs that could have induced significant measurement errors. Increased failure rates have been demonstrated in knees with femoral component flexed greater than three degrees [111]. Therefore, although flexion of the femoral component confers increased knee flexion, the risk of early aseptic failure diminishes any significant clinical benefits. Therefore, this study demonstrates that within the therapeutic range of femoral component flexion, we could potentially achieve 0.9 degrees of increased flexion and 0.6 degrees of ROM, which would not be considered clinically significant. Moreover, a theoretical disadvantage to flexing the femoral component is loss of knee extension. However, this and previous studies do not demonstrate any statistically significant association between FCA and MEA [94].

Thickened posterior femoral condyles are a common design feature in contemporary "high-flex" TKA implants. This study demonstrates that PCO is a statistically significant predictor of MFA in patients with osteoarthritis who underwent primary TKA using a posterior cruciate retaining implant. An increase of 1mm of posterior condylar offset resulted in 0.2 degrees of increased flexion with the potential to contribute atleast 4 degrees of overall flexion and therefore has minimal clinical implications in implant design and intra-operative implant positioning. This is consistent with the finding by previous authors that PCO is a predictor of knee flexion [99, 112]. This could be because increased PCO allows increased flexion prior to direct impingement between the posterior margin of the tibial component against the posterior aspect of the femoral component. However, this is in contradiction to cruciate sacrificing TKA studies that demonstrated no correlation between PCO and post-operative knee flexion [100, 113]. This could be because the inability to maintain or restore a functional posterior cruciate ligament might contribute to a paradoxical anterior translation of the femur during flexion resulting in earlier impingement and hence reduced flexion. Further studies investigating the influence of PCO on knee flexion in cruciate retaining and sacrificing prostheses would be warranted. There is a theoretical risk that excess PCO in TKA reduces flexion gap due to relative shortening of posterior soft tissue contributing to post-operative flexion contractures [114]. This could explain why the increased PCO, despite increasing the MFA, did not translate into statistically significant increase in ROM. However, this study and previous studies do not demonstrate any statistically significant association between PCO and MEA [115]. A further examination of outlier PCO in TKA patients may be warranted to conclude on any association between PCO and post-operative flexion contractures.

The desired tibial sagittal alignment for most prostheses is a posterior slope between zero and seven degrees which can be achieved by bony resection or if the posterior slope is built into the polyethylene [110]. An early cadaveric study by Bellemans et al, demonstrated that one degree increase in posterior TS would increase the MFA by an average of 1.7 degrees [98]. This study did not find any statistically significant association between TS and knee kinematic variables in patients with osteoarthritis who underwent primary TKA using a cruciate retaining implant. However, this is in contradiction to recent clinical studies that demonstrate no correlation between TS and post-operative knee kinematics in cruciate sacrificing TKA; and a demonstrable correlation if the cruciate ligaments are preserved [100, 102, 116]. It is thought that increased posterior TS increases tension on the posterior cruciate ligament facilitating posterior femoral translation and femoral roll back, thus increasing knee flexion [116]. However, this correlation between increased TS and MFA (2.3 degrees of increased flexion per degree increase in tibial slope) in cruciate retaining prosthesis was only demonstrable from one to six degrees of posterior tibial slope after which it plateaus [116]. The lack of correlation in our study cohort could be attributed to the fact that greater than 50% of our participants had tibial slope < 1 degree or > 6 degree, which is outside the window of correlation demonstrated by Chambers et al [116]. Given that the influence of TS on knee flexion can only be demonstrated in a controlled cadaveric setting, with previous authors failing to demonstrate any correlation in cruciate sacrificing studies and a narrow window of correlation in cruciate retaining studies, the clinical significance of the influence of TS on knee kinematics may be negligible.

The prediction models for knee kinematics (MEA, MFA and ROM) achieved low variance, suggesting that other untested variables may contribute more significantly to post-operative kinematics. The final knee kinematics is the culmination of a complex set of multi-factorial interactions, not limited to pre-operative kinematics, component alignment in the coronal plane, component size, bony resection and soft tissue release, with each specific factor contributing very little to kinematics individually [63, 65]. However, this study demonstrates that FCA is a significant predictor of MFA and ROM; and PCO is a significant predictor of MFA.

6.2 Hypothesis 2

The most important finding of this study is that TUG is a moderate predictor of balance in single leg stance with eyes open in patients with osteoarthritis who underwent primary TKA using a posterior cruciate retaining implant. Balance is considered an important outcome measure, as it is highly predictive of the quality of life and function of patients after TKA [22]. The findings of this study are consistent with that previously demonstrated by Schwartz et al who performed static balance measures in patients after TKA; they demonstrated a significant (R^2=0.51, p<0.001) association between TUG and their static balance measures [22].

Patients who undergo TKA demonstrate improved single leg balance when compared to those with high tibial osteotomy [23]. This is because restoration of joint space facilitates re-recruitment of dynamic knee stabilizers to facilitate restoration of proprioception and balance which in turn improves functional mobility that is measured by TUG [23]. This association between TUG and balance helps explain why TUG is indicative of a prior history of falls, and why TUG is also considered a reliable and valid measure of change in functional mobility of inpatients on orthopaedic wards [81, 82].

However, this association with TUG was not reflected in balance when tested with two legs, either with eyes open or with eyes closed. Butler et al demonstrated that patients with total ankle arthroplasty had significantly poorer balance compared to those following hip or knee arthroplasty, suggesting the greater importance of the ankle in maintaining balance [117]. Hence, a possible explanation is that in two-legged stance the contralateral leg, particularly the ankle, provides sufficient afferent input to avoid increased sway, confounding any association between balance and TUG.

The influence of ROM and isometric flexion and extension strength on balance in patients post TKA has never previously been investigated. Although flexion strength in this study was found to be the most significant contributor to balance with two legs, both with eyes open and closed, it did not achieve statistical significance. Corrigan et al demonstrated a significant correlation between hamstring to quadriceps ratio and balance in ACL deficient knees, suggesting a relatively greater correlation of flexion strength in comparison to extension strength with functional outcome in patients [103, 104]. However, Lee et al could not demonstrate a statistically significant correlation between hamstring strength and balance in patients with ACL deficient (Rho=0.239, p=0.506) and ACL intact (Rho=0.367, p=0.297) knees [105]. One possible explanation could be that the contribution of dynamic hamstring muscles is only clinically relevant in high intensity activities like running or uphill walking [17]. Hence, hamstring strength is unlikely to be a significant contributor to static balance, but is relatively more important than quadriceps strength in maintaining balance post TKA.

A change in joint position causes a change in muscle length or velocity, and this initiates a stretch reflex at the level of the spinal cord [118]. Intrafusal muscle fibres convey impulses via gamma motor neurons to monosynaptically transmit signals via alpha motor neurons that then cause contraction of the extrafusal muscle fibres [118]. This forms much of the basis of quadriceps strengthening exercises by physiotherapists post TKA. Quadriceps weakness is intrinsic to the pathogenesis and natural progression of osteoarthritis with an immediate decline in the strength of the extensor mechanism immediately post TKA, followed by significant improvement subsequently which plateaus after six to twelve months [71]. This study demonstrates that extension strength is not a predictor of balance in patients post TKA. This could be because in elderly patients and those with osteoarthritis who have lost the proprioceptive ability of the knee, proprioception is predominantly mediated supraspinally, communicated by the posterior column-medial lemniscus pathway to the cerebrum or dorsal and ventral spinocerebellar tract to the cerebellum [118]. Stevens-Lapsley et al demonstrated that despite a faster improvement in muscle strength following minimally invasive TKA, this did not translate into improved functional performance [119]. Moreover, decreased EMG amplitudes in the vastus lateralis and biceps femoris in patients post TKA compared to control patients with OA, suggests that the improvement in proprioception and balance could be secondary to relative over-recruitment of other dynamic knee stabilizers [23]. Hence, it is possible that while a minimum quadriceps and hamstring strength is paramount for ranging the knee, particularly when being loaded without "giving way", any further strength gain might not add to functional performance.

This study also demonstrates that ROM is not a predictor of balance in patients post TKA. Watanabe et al demonstrated that intra-operative joint gaps at 120-135 degrees and at 10 degrees of flexion was positively correlated with post-operative flexion and extension respectively, to emphasise the importance of joint gaps at flexion and extension to preserve or increase ROM [120]. Although it is suspected that greater joint gaps and soft tissue imbalance could adversely affect joint stability, it has been demonstrated that the clinical range of joint gaps do not affect balance [120]. Hence, it could be that ROM and balance share a non-linear relationship where the majority of clinically significant ROM has minimal or no impact on balance; a further study of outlier ROMs would be required to determine the tipping point of balance. Moreover, Pua et al demonstrated that knee extensor strength is significantly correlated with extension ROM and mediates the influence of knee ROM on physical function [69]. As extension strength is not a predictor of balance, ROM would not be significantly associated with balance.

The small value of the coefficient of determination (R^2) achieved by these regression models and the inability to achieve statistical significance suggests that ROM, flexion strength, and extension strength are not significant predictors of balance. This is unlikely to be a Type II error, and is possibly explained by other unexamined factors that could contribute more substantially to balance. However, the more likely explanation is that balance is the culmination of a complex set of multi-factorial interactions, with each specific factor contributing very little to balance individually.

6.3 Hypothesis 3

Total knee arthroplasty (TKA) is cost effective and highly successful in the management of arthritic knees with a 94.4% ten year implant survival rate [121]. Recently, the Swedish, United Kingdom and New Zealand national joint registries have adopted PROMs as cost-efficient, reproducible and reliable tools to report patient satisfaction and hence the success of TKA [1, 12]. However, despite the improved implant survival, decreased revision rates and exceptional objective outcomes after total knee arthroplasty (TKA), there is evidence that up to 23% of patients are dissatisfied with their replaced knee [1]. There is very little understanding of the relationship between subjective and objective functional outcome measures used in TKA patients. The most important findings of this study are that TUG and ROM are both significant predictors of patient satisfaction after TKA.

The results of this study demonstrate that ROM is a statistically significant moderate predictor of OKS, suggesting that patient satisfaction improved with increased ROM as previous authors have demonstrated. Pua et al demonstrated a correlation between flexion ROM and SF-36 physical function, and Christen et al demonstrated positive correlations for ROM with both the Knee Injury and Osteoarthritis Outcome Score (0.33) and the Knee Society Score (0.40) [122, 123]. Increased patient satisfaction in patients who achieved increased ROM could be a reflection of the increased functional ability particularly in the Asian population who frequently use high flexion in activities of daily living [16]. Laubenthal et al demonstrated that a minimum ROM of 90 degrees is required for activities of daily living, with higher-level activities like running and cycling dependent on increased ROM [15]. However, Thomsen et al demonstrated no relationship between ROM and the ability to perform activities of daily living [106]. This could be because all of Thomsen's participants achieved >95 degrees of flexion [106]. Hence, achieving ROM of at least 90 degrees is crucial for post-operative patient satisfaction, but any further gains are most likely clinically irrelevant in the elderly, Caucasian cohort.

The results of this study also demonstrate that TUG is a statistically significant moderate predictor of OKS, suggesting that the faster a patient could complete the TUG test, the more satisfied the patient was post-operatively. Rossi et al demonstrated a similar correlation for TUG with the aggregate WOMAC score (0.59) and physical function dimension (0.63) [124]. This could explain why TUG is considered a reliable and valid measure of change in functional mobility of inpatients on orthopaedic wards and hence would reflect patient satisfaction [81]. However, Beard et al demonstrated that a difference of nine points for cohort studies and four points for case-control studies is the minimum clinically significant difference for OKS, suggesting that the correlations for ROM and TUG with OKS, though statistically significant, may not be clinically significant [125]. Hence, it is possible that functional outcome measures do not substitute for, or are not predictive of, PROMs but are instead complementary to patient satisfaction in measuring outcomes after TKA.

This study also found that isometric flexion and extension strength are not statistically significant predictors of patient satisfaction. This could be because of a non-linear association between extension strength and physical function, with a strength threshold below which the muscle strength and physical function are closely related, but above which the association is diminished [122]. Moreover, the contribution of dynamic hamstring muscles is only clinically relevant in high intensity activities like running or uphill walking, and again may not be appreciated by the typical geriatric recipients of TKA [17]. This study demonstrates that balance is not a statistically significant predictor of patient satisfaction. This contradicts the findings by Schwartz et al, that static and dynamic balance measures were statistically significant predictors of SF-36 and OKS [22]. However, the study by Schwartz et al was limited by a high dropout rate of 24.3% and compliance between 62% and 68% for PROMs, introducing significant attrition and selection bias due to the elimination of patients who may have had poor post-operative outcomes. In those patients who have already become compliant with the use of mobility aides during the lengthy lead-up to surgery, further balance gains may not translate into patient satisfaction [126]. Moreover, it is possible that increased reliance on the contra-lateral limb, to negate the pre-operative loss of balance related to the arthritic knee, may then result in a failure of the patient to appreciate any subsequent balance gains resulting from the TKA.

The prediction model for Oxford Knee Score achieved low variance (35%), suggesting that other untested variables may contribute more significantly to subjective patient satisfaction post TKA. Post-operative patient satisfaction is the culmination of a complex set of multi-factorial interactions, not limited to post-operative pain, stiffness, perception of alignment, ROM and functional ability, with each specific factor contributing very little individually to overall patient satisfaction [127].

6.4 Limitations

Hypothesis 1 has certain limitations. It is thought that measurement of PCO on radiographs do not correlate with those of the medial or lateral condyles on computed tomography (CT) [128]. However, CT exposes patients to higher radiation, cannot be utilised in patients who are claustrophobic or cannot lie still for the duration of the test and is susceptible to significant component artefacts predisposing to measurement errors. Hence, this study utilized true lateral radiographs taken by a single senior radiographer to a pre-determined protocol on the first day post operation for measurement of sagittal plane component alignment. Numerous confounders are thought to influence post-operative kinematics. Pre-operative diagnosis and ROM are considered the most significant predictors of post-operative ROM [65]. Moreover, previous authors have investigated numerous factors not limited to age, sex, body mass index, patellar thickness and height, component size and design, posterior cruciate ligament status and radiological alignment for association with knee kinematics, with conflicting evidence in literature [65, 129]. This study was limited to non-obese patients with osteoarthritis undergoing primary cruciate retaining TKA with a standardized implant design in order to minimize confounders. Moreover, this study accounted for age, gender and pre-operative kinematics to mitigate the influence of confounders. While male participants demonstrated 2.147 degrees of increased flexion in comparison to female participants, other variables failed to demonstrate any statistically significant influence on post-operative knee kinematics. Furthermore, the influence of gender can be explained by the need for larger prosthesis in males resulting in increased PCO and hence knee flexion. Therefore, this was a carefully designed prospective study to minimise the influence of confounders while maintaining the external validity. It is possible that the combination of FCA, PCO and TS may be more important in determining post-operative knee kinematics, rather than in isolation, with deviation of one value being remedied by alteration of the others. Future studies should strive to investigate each of these variables by controlling the other variables in neutral position.

Moreover, Hypothesises 2 and 3 also have certain limitations. Systemic inflammatory arthritis such as rheumatoid arthritis could potentially result in different outcomes and influence outcome measures. The effect of chronic inflammatory disease on outcome is not well established, with some studies reporting better outcomes in patients with rheumatoid arthritis and others in patients with osteoarthritis [64, 130]. The pre-operative levels activity levels and duration of post-operative physiotherapy were not controlled due to the retrospective design of the study; both these variables could have potentially influenced our results. However, there are no pre- or post-operative physiotherapy protocols that can be universally applied to all TKA patients due to the highly individualised deficits and pathology, rendering futile most attempts to standardize these variables [131]. Similarly, the Body Mass Index of patients could also be considered a potential confounder of outcome. However, Napier, et al (2014) showed that morbidly obese patients did not have a statistically significantly greater complication rate compared to non-obese patients [132]. Patient recruitment from a single institution, as opposed to a multi-center study, and the convenience sampling employed for participant selection may be considered to weaken the external validity of the study. However, close examination reveals that participant characteristics such as age, side and gender distribution, incidence of bilateral TKA, and others are closely reflective of the general population, thus preserving the external validity of the study.

6.5 Internal and External Validity

6.5.1 Internal Validity:

The research project limited investigation to participants with a single implant design. Different implants designs are a confounding factor that can affect the navigational kinematic data and the clinical outcome. Standardizing the implant design strengthens the internal validity of the research, but weakens the external validity.

Selection of participants was dependent upon the follow-up of patients. Patients who presented to the follow-up clinic were invited to take part in the research. Although no patients declined the invitation to participate, the research did not include patients who failed to turn up to follow-up clinic. It is difficult to postulate if loss to follow-up was due to the lack of interest of high functioning patients or the inability of poorly mobilising patients. However, this introduces a selection bias due to loss to follow-up.

6.5.1 External Validity:

CAS TKA is performed at RBH by two different orthopaedic surgeons and there was no set operative protocol. Although the surgical procedure is standardized, the varying skill levels of the different surgeons could influence the outcomes. However, the use of more than one surgeon strengthens the external validity of the research project.

Hawthorne effect – it is likely that participants might outperform their general performance levels during investigation. This is likely to result in falsely elevated results that cannot be generalised to the entire population.

6.6 Conclusion

The most important finding of this study is that the femoral component angle in the sagittal plane is predictor of knee flexion and range of motion. Given the increased risk of implant failure with greater than three degrees of flexion, the clinical relevance of femoral component flexion might be limited. Another important finding is that the posterior condylar offset is also a predictor of knee flexion. However, the benefits of increasing the PCO might be limited to only 4 degrees of increased flexion in cruciate retaining TKA with a theoretical risk of flexion contractures. It is important to note that this study failed to demonstrate a statistically significant correlation between tibial slope and knee kinematics. Although in vitro studies have shown tibial slope to influence knee kinematics, the lack of this observation in cruciate sacrificing studies combined with a narrow window of correlation (zero to seven degrees of posterior tibial slope) in cruciate retaining studies, suggest that its clinical relevance might be limited.

This study suggests that TUG is a moderately significant predictor of balance on a single leg following TKR. Knee flexion strength, knee extension strength, and ROM do not contribute significantly to balance following TKR, for either single or two-leg stance. The results of this study also suggest that TUG and ROM are both statistically significant predictors of subjective patient reported outcomes following TKA. Despite the functional benefits of flexion strength, extension strength, and balance in patients after TKA, these functional outcome measures may not contribute significantly to post-operative patient satisfaction. Functional outcome measures are complementary to PROMs in measuring post-operative outcome. Further investigations are warranted to determine what additional factors may contribute significantly to patient satisfaction after TKA.

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